

[http://www.cirs-reach.com/news/China\\_SFDA\\_publishes\\_draft\\_guidelines\\_for\\_the\\_registration\\_and\\_evaluation\\_regarding\\_cosmetics\\_for\\_children.html](http://www.cirs-reach.com/news/China_SFDA_publishes_draft_guidelines_for_the_registration_and_evaluation_regarding_cosmetics_for_children.html)

## China SFDA publishes draft guidelines for the registration and evaluation regarding cosmetics for children

15 Feb 2012, China SFDA (State Food and Drug Administration) has launched draft guidelines for the registration and evaluation of cosmetics for children in China. The deadline for public comments is 29 Feb 2012. The Guidelines have outlined the main factors to consider during the evaluation and approval of new cosmetics for children under 12 years old (including babies).

### Background

The lack of guidelines regarding the safe evaluation of cosmetics for children is a global issue. Occurrences in China are no exception.

In the USA, with the exception of color additives and cosmeceuticals, regular cosmetic products and ingredients are not required to be registered before being placed on the market in the light of current laws. Manufacturers test their own ingredients and ensure product safety but do not have to inform this to the Food and Drug Administration (FDA). There are no specific guidelines for the safety evaluation of cosmetics for children.

In Europe, the European Commission has also not issued any specific legislation regarding cosmetics for children. Only a specific assessment for cosmetics intended for use on children under the age of 3 is required for the notification documents since November 2004. However, French Health Agency (AFSSAPS) has highlighted the lack of guidelines for safety evaluation and has launched recommendations on safety evaluation of baby care products in April 2010 for a better harmonization of regulatory requirements within EU. The manufacturers must/ shall take into account the following aspects for the safety assessments of cosmetics for children under the age of 3:

- the fact that, proportionally to their mass, the body surface of children of 0-3 years is more important than that of adults and that functional maturity of the metabolic systems may not be stabilized before 2 years of age,
- certain specific conditions of exposure, especially at the level of the seat area, which is highly exposed,
- the different types of products, especially not-rinsed products that can be applied several times a day with no limit.

In China, quality issues regarding baby care products have occurred frequently during the past two years. Since April 2010, none of the imported baby care products have been approved by the SFDA. The lack of guidelines for the registration and evaluation of cosmetics for children is sighted as the main reason. Thus China has also followed AFSSAPS's recommendations and drafted the guidelines for comments.

### Scope

The Guidelines apply to cosmetics intended for children under the age of 12.

### Requirements of Product Formulations

The following principles shall be followed when formulating cosmetics for children:

- trying to use the lowest number of ingredients;
- achieving product performance with less or without perfumes, colorants, preservatives and surfactants, as well as paying attention to potential sensitization hazard;
- avoiding efficacy ingredients used for whitening, freckle removal, anti-acne, hair removal, hydroschesis, deodorization, hair grow, hair dye, fitness and breast shaping;
- choosing ingredients and technology with a history use sufficient to ensure safety. New technique and advanced materials such as gene technology and nanomaterials are not encouraged for use;

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- understanding the source, composition, impurity, physio-chemical properties, scope of applications, safety dose and other information of each ingredient in formulations

### Extra Testing Requirements

- Phototoxicity, sensitisation, skin and eye irritation: The formulations shall not have any relevant adverse effects;
- Microbial test. The total plate count shall not exceed 500CFU/mL or 500CFU/g.

### Labeling and Packaging

Chinese product name, labeling and instruction for use shall contain clear statements such as "intended for use on children". Meanwhile warning statements like "intended for use on children, must be used under the supervision of an adult" shall also be marked on the outer packing.

### Safety Evaluation and Notification Materials

Companies who would like to register cosmetics intended for use on children shall provide

- A specific safety assessment of products and their ingredients based on the characteristics of children use;
- Extra safety assessment of perfume, organic solvent, cationic surfactants, penetration enhancers and other ingredients depending on how cosmetics is used (for example, whether a cosmetic product is to be rinsed or not after use);
- Design principles of product formulations (including analysis report);
- Principles and requirements of selecting ingredients.

Companies who formulate and register their cosmetics for use on children in China shall follow the above guidelines. They shall also comply with the requirements of Hygienic Standards for Cosmetics (2007) which has restricted or banned dozens of ingredients in cosmetics intended for use on children.

No	Name	Field of application and /or use	Ingredient labeling requirement
1	safrole		not present in toothpastes intended specifically for children
2	alkali sulphides and alkaline earth sulphides		
3	Boric acid, borates and tetraborates	1. Talc 2. Products for all hygiene 3. Other	Not to be used in products for children under 3 years of age

	with the exception of substance in table	products (excluding bath products and hair waving products)	
4	Tetraborates	<ol style="list-style-type: none"> <li>1. Bath products</li> <li>2. Hair waving products</li> </ol>	<ol style="list-style-type: none"> <li>1. Not to be used in products for children under 3 years of age</li> </ol>
5	Calcium hydroxide	<ol style="list-style-type: none"> <li>1. Hair straighteners</li> </ol> <p>(b) pH adjuster — for depilatories (c) Other uses(eg. pH Adjuster, processing aid)</p>	
6	Cantharides tincture	Hair growth	Not to be used in products for children
7	Lithium hydroxide	<ol style="list-style-type: none"> <li>1. Hair straighteners</li> </ol> <p>(b) pH adjuster — for depilatories (c) Other uses—as pH adjuster (for rinse-off products only)</p>	
8	Potassium or sodium hydroxide	<ol style="list-style-type: none"> <li>1. Nail cuticle solvent</li> <li>2. Hair straightener</li> <li>3. pH adjuster— depilatories</li> </ol> <p>(d) Other uses as pH adjuster</p>	
9	Salicylic acid	a) No-rinsed products and rinsed-off skincare products	Not to be used in cosmetics for children under

		b) Rinse-off hair products	three years of age, except for shampoos
10	Strontium acetate hemihydrate	Toothpaste	
11	Strontium chloride hexahydrate	(a) Toothpaste (b) Shampoo and face care products	
12	Strontium hydroxide	pH-regulator in depilatory products	
13	Talc: Hydrated magnesium silicate	(a) Powdery products intended to be used for children under three years of age (b) other products	
14	Thioglycollic acid and its salts	(a) Hair waving or straightening products  1. Depilatories 2. Other hair-care  products which are removed after application	
15	Thioglycollic acid esters	Hair waving or straightening products	
16	Salicylic acid and its salts (as preservatives)		Not to be used in cosmetics for children under three years of age, except for shampoos
17	Silver chloride deposited on titanium dioxide(as preservatives)		