GPC
Global Product Compliance

Cosmetic ingredients management in newly regulations of China

Europe | India | South Korea | Eurasia | Turkey | UK | Taiwan | Australia | Ireland

Content

Cosmetic ingredients management

ECI

NCI

Pre-market approval

Inventory of ECI (2021 version) （*IECIC*）

Highly risk ingredients

Safety and Technical Standards for Cosmetics（2015）(*Standards*)

Highly risk

Lowly risk

★ECI: Existing Cosmetic Ingredients
NCI: New Cosmetic Ingredients

Forbidden components

Restricted components

Approved components （antiseptic, sunscreen, coloring, hair dyeing）

Registration

Record

Post-market supervision

Similar to Regulation (EC) No 1223/2009 *ANNEX II-VI*

If there is no safety problem after 3-year safety monitoring period, it shall be included in IECIC

Cosmetic ingredients management

No	Chinese name	INCI name/English name	Rinse-off cos. highest use amount	Leave-on cos. highest use amount	Remarks
00010	1,5-萘二酚	1,5-NAPHTHALENEDIOL	/	/	按照《化妆品安全技术规范》要求使用
00011	1,5-戊二醇	1,5-PENTANEDIOL		10	
00012	1,6-己二醇	HEXANEDIOL		6	
00013	1,9-壬二醇	*1,9-NONANEDIOL*			
00014	10-羟基癸酸	10-HYDROXYDECANOIC ACID		1	
00015	1-甲基乙内酰脲-2-酰亚胺	1-METHYLHYDANTOIN-2-IMIDE		2.5	
00016	1-萘酚	1-NAPHTHOL	/	/	按照《化妆品安全技术规范》要求使用
00017	1-羟乙基-4,5-二氨基吡唑硫酸盐	1-HYDROXYETHYL 4,5-DIAMINO PYRAZOLE SULFATE	/	/	按照《化妆品安全技术规范》要求使用
00018	2,3-丁二醇	2,3-BUTANEDIOL		13.05	
00019	2,4-二氨基-5-甲基苯氧基乙醇盐酸盐	2,4-DIAMINO-5-METHYLPHENOXYETHANOL HCL	/	/	《化妆品安全技术规范》禁用组分
00020	2,4-二氨基-5-甲基苯乙醚盐酸盐	2,4-DIAMINO-5-METHYLPHENETOLE HCL	/	/	《化妆品安全技术规范》禁用组分

Used according to the Standards

Approved hair dye

Forbidden component

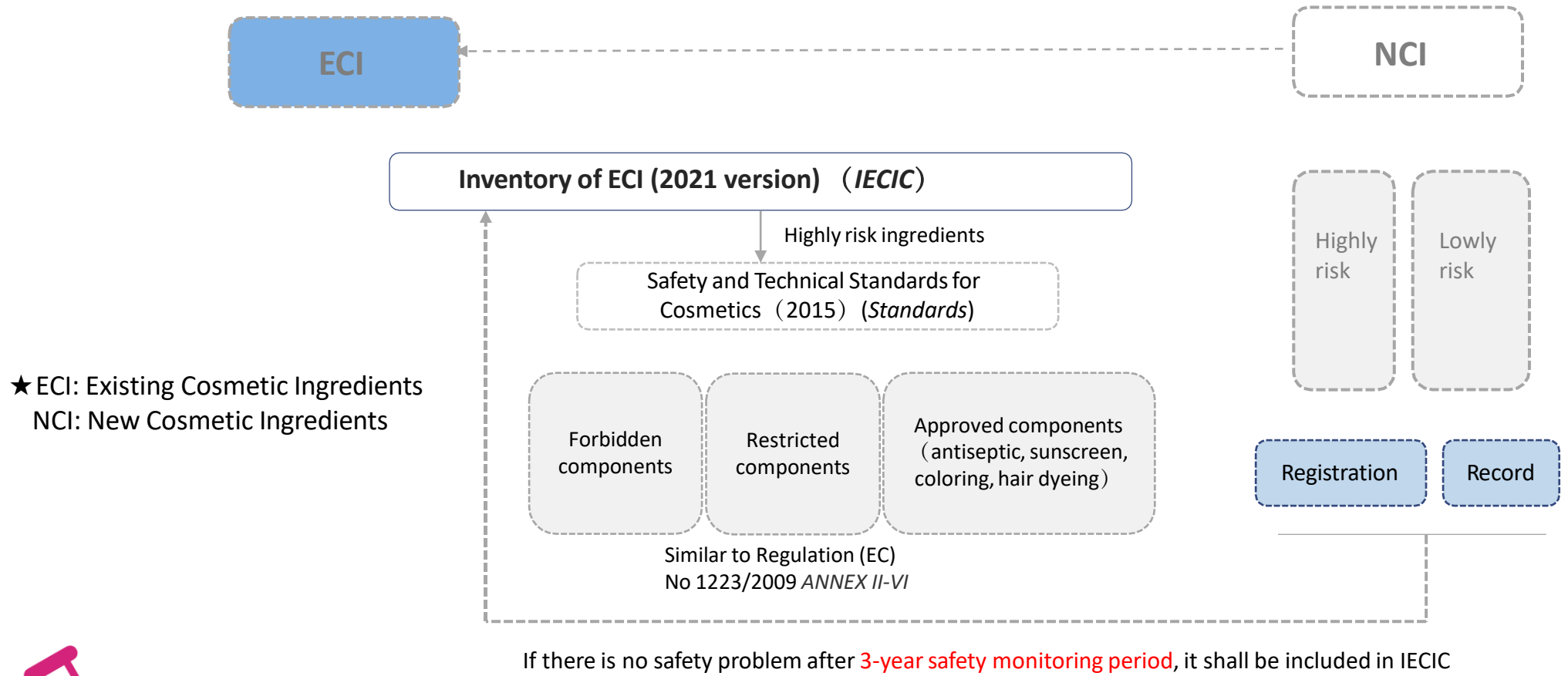
Inventory of ECI (2021 version) (*IECIC*)

- When we inquire whether an ingredient can be used in cosmetics, we not only need to inquire IECIC, but also need to consider the Standards. Besides, we shall screen that some of the name in the catalogue appear as class name.

- Such as:

✓ WATER-SOLUBLE ZINC SALTS are listed in the restricted components. Therefore, ZINC ACETATE , ZINC COCETH and such shall meet the restriction requirements.

✓ TRIETHANOLAMINE has been listed in IECIC, and the remark is "use in accordance with the requirements of the Standards". When we search the name directly in the Standards, you can't find the substance. In fact, it has been listed in the restricted component No. 11 (tri chain alkanolamine, tri chain alkanolamine and its salts), which needs to be used in accordance with the restricted requirements.



★ECI: Existing Cosmetic Ingredients
NCI: New Cosmetic Ingredients

If there is no safety problem after 3-year safety monitoring period, it shall be included in IECIC

Manufacturer

Safety and Technical Standards for Cosmetics（2015）(Standards)

3.8 ingredient requirements

It specifies the requirements for safety, quality, technique, package, label, ingredients from animals and plants and new ingredients for cosmetics

Administrative Measures for the Registration and Record of Cosmetics

Issue safety information file (SIF) to cosmetics manufacturers; Or submit SIF on the cosmetic ingredients safety information registration platform (hereinafter referred to as the platform), to get submission code, and authorize cosmetics manufacturers to use it.

Cosmetics manufacturers

Regulations on Supervision and Administration of Cosmetics

Establish ingredients acceptance management system and incoming inspection record system and such, to ensure that the ingredients used comply with national standards and technical specifications. If the use of ingredients is illegal, there will be strict punishment provisions (refer to Chapter V)

Administrative Measures for the Registration and Record of Cosmetics

Upload SIFs of all the ingredients-except ordinary water, when registering or record cosmetics; Or relate to each submission code of ingredients.

Cosmetic ingredients management

★ECI: Existing Cosmetic Ingredients
NCI: New Cosmetic Ingredients

ECI

NCI

Inventory of ECI (2021 version) （*IECIC*）

Highly risk ingredients

Safety and Technical Standards for Cosmetics（2015）(*Standards*)

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Similar to Regulation (EC) No 1223/2009 *ANNEX II-VI*

Highly risk

Lowly risk

Registration

Record

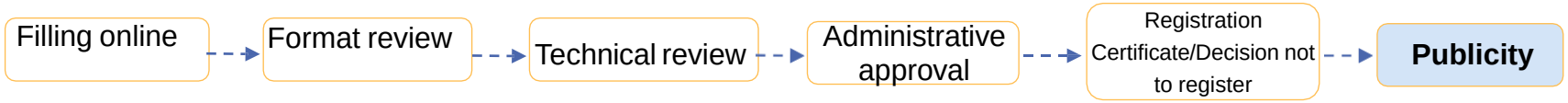
If there is no safety problem after 3-year safety monitoring period, it shall be included in IECIC

NCI

NCIs with high safety risk: Registration (antiseptic, sunscreen, coloring, hair dyeing, freckle removing and whitening functions)

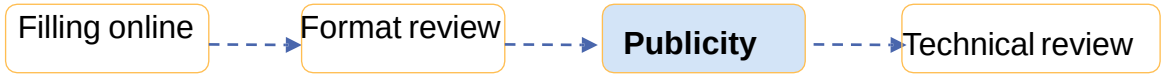
Other NCIs: Record

Registration process:



Record process:

years.



When the NCIs have been registered or record successfully, they can be used in cosmetics by the applicant or authorized enterprise. It enters the 3-year safety monitoring period. If there is no safety problem during the period, it will be included in IECIC after three years.

NCI

Before the registered and record NCIs are included in IECIC, they shall still be managed as NCIs

If the purpose of use and safe use amount of the ECI are adjusted, Registration and Record of new ingredients shall be applied for in accordance with the requirements

Tips：

- **For the same ingredient**, if company A completes the registration or record, it shall be used by company A and its authorized enterprises in accordance with the published technical requirements;
- If company B wants to use the ingredient for the same purpose and use amount, it needs to obtain the authorization of company A or apply on its own, or use it after it is included in IECIC.
- If company C wants to use the ingredient with different purpose or use amount, it needs to apply on its own. Meanwhile, the safety monitor period is not consistent with company A.

Applicant

- It is not specified that it must be the manufacturer, but considering the strict data requirements, it is generally applied by the manufacturer.

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For overseas registrants and recorders, it is necessary to appoint a domestic enterprise legal person as local responsible unit (LR) to perform the following obligations:

1. Register and record NCIs and cosmetics in the name of the registrant or recorder;
2. Assist on adverse reaction monitoring of cosmetics, safety monitoring and reporting of NCIs;
3. Assist on implementing the recall of cosmetics and NCIs;
4. Take the corresponding quality and safety responsibility for cosmetics and NCIs put on the domestic market according to the agreement between Overseas Registrant/Recorder and LR;
5. Cooperating with the supervision and inspection work of the drug supervision and management department.

Applicant

- Suggestion for LR

  - ✓ LR is set for the overseas applicant, not for the imported products. Therefore, if it is an overseas applicant with domestic products, it also needs a LR; If it is a domestic applicant and the product is imported cosmetics, LR is not required.

  - ✓ As LR not only needs to handle the application in the name of the registrant and the recorder, but also needs to fulfill the obligations of assisting in adverse reaction monitoring, implementing product recall, assuming corresponding quality and safety responsibilities in accordance with the agreement, and bearing corresponding legal responsibilities. Therefore, it is very important to select the suitable domestic enterprises as LR.

Dossier list

Data requirement	
I. Basic information	1. Information sheet of ingredients registered or recorded
II. Research report	2. R&D background
	3. Basic information of ingredients
	4. Information on the use of ingredients①
	5. Information on the functional basis
	6. Other information relevant to the development
III. Preparation process and quality control standards	7. Brief description of the preparation process
	8. Stability test data
	9. Quality specification indicators and their test methods
	10. Information on possible safety risk substances and their control, etc. ②
IV. Safety evaluation	11. Review of toxicological safety evaluation
	12-23. Toxicology test reports
	24. Safety evaluation reports
V. Other information	25. Technical requirements of new ingredients
	26. Other information that contributes to the registration and record of new cosmetic ingredients⑦

About function (1)

Function selected:

- The functions of NCI need to be selected from the drop-down menu. This option may be added when the system is updated. At present, there are 67 functions available for selection, and you can choose more than one for our application.

- It should be noted that the surfactant often selected by clients is not one of the options. We need to determine the specific functions, such as detergent, foaming agent and so on.

pH adjuster	Antidandruff agent
Deodorant agent	Solvent
Hair conditioning agent	Emulsifying agent
Hair fixative	Humectant
Flavoring agent	Emulsion stabilizer
Preservative	Emollient
Sunscreen agent	Astringent
Dispersant	Bulking agent
Occlusive agent	Propellant
Chelating agent	Adsorbent
Reducing agent	Absorbent
Buffering agent	Denaturant
Keratin peeling agent	Antifoaming agent
Keratin softeners	Suspending agent
Anticaking agent	Oxidizing agent
Epilating agent	Antiperspirant agent
Antistatic agent	Thickener
Antioxidant	Solubilizer
Cleansing agent	Binder
Algefacient	Pearlescent agent
Freckle agent	Surface modifier

About function (2)

Scientific literature	Regulatory information
Laboratory research data	Human efficacy evaluation test data

Function basis:

- In terms of functional basis data, it is actually difficult to use literature. Detailed test data and analysis of research results are needed to prove the correlation between the declared substance and function. For ingredients with ordinary functions, we suggest to provide laboratory research data, which can be proved by physical tests.

- For NCIs that claim the functions of **anti-corrosion, sunscreen, freckle whitening, hair loss prevention, acne removal, non-physical anti wrinkle, dandruff removal and deodorization** shall provide at least include laboratory research data or human efficacy evaluation test data

About tests

Stability test data	Quality specifications
Toxicological tests	Functional basis tests

- **Laboratory qualification requirements**: toxicological tests and evaluation tests of anti-corrosion, sunscreen, freckle whitening and anti hair loss efficacy should be carried out by CMA, CNAs in the field of cosmetics or institutions in line with GCP and GLP. Other tests have no special requirements for laboratory qualification, and can be carried out by themselves or entrusted to institutions with corresponding capabilities.

Test method requirements:

1.Toxicological tests shall be carried out in accordance with the Standards. Methods other than those specified shall be carried out in accordance with national standards or internationally accepted methods, such as OECD methods.

2.In principle, other test methods shall refer to the methods in the Standards or Chinese Pharmacopoeia. Methods other than those specified shall be carried out in accordance with national standards, internationally accepted methods or self-developed test methods.

Compliance requirements for new cosmetic ingredients (Platform)

- Cosmetics registration and record information service platform (https://zwfw.nmpa.gov.cn)

Compliance requirements for new cosmetic ingredients (Platform)

Enterprise information management module: Handle the information submission, maintenance, cancellation of cosmetics and NCIs enterprises

Cosmetics smart application and review module: Handle registration work of special cosmetics, registration/record work of NCIs.

Ordinary cosmetics management module: Handle record work of ordinary cosmetics.

Enterprise information management module

User types

- Cosmetics user
- NCIs user

Cosmetics Role types

- Registrant/ Recorder
- LR
- Manufacturer

NCIs Role types

- Registrant/ Recorder
- LR

Compliance requirements for new cosmetic ingredients (Platform)

- Enterprise information management module

Role type	Information sheet
Registrant/Recorder	Registrant/Recorder Information sheet
	safety risk monitoring and evaluation system overview sheet
LR	LR Information sheet
	Information of Overseas registrant/recorder • Authorization letter • Overseas registrant/recorder information sheet • Safety risk monitoring and evaluation system overview sheet

Cosmetics smart application and review module

Including special cosmetics registration, NCIs application, monitoring period management of NCIs, authorization management of NCIs, confirmation of entrustment relationship, etc.

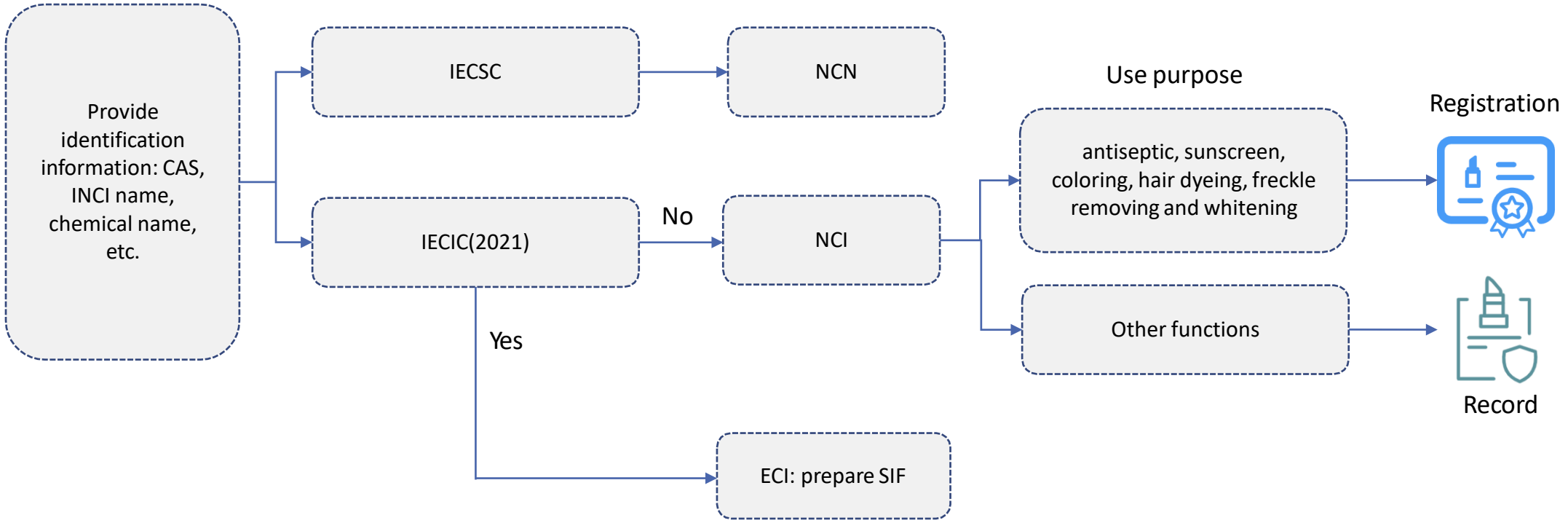
Cosmetics smart application and review module

Fill in the product information on the platform, and submit relevant attachments

Summary: Supervision of cosmetic ingredients

		Pre-market	Post-market		
			Annual report	SIF	Change, etc.
NCIs	high risk	registration	√（3 years）	×	reapplication (for adjusting the use purpose, safe use amount, etc. of used cosmetic ingredients)
	Others	record			
ECIs	-	-	×	√	

Summary: Compliance procedures



About GPC

*"Our capacity has gone from **local** to **global**."*

We were founded in 2008, Lund Sweden.

We offer excellent representative and compliance management services globally.

8 offices worldwide & 2 laboratories

Today, we have more than 1500 happy clients worldwide, 99% retention rate.

Services



We have an elaborative portfolio of 15,000+ substances.

Authoring a large portfolio of 5,000+ REACH and 500+ CLP compliant SDS and e-SDSsin 30+ languages.

750+ Lead registration & consortia management.

"We have followed our clients to new countries and markets which has made us expand our business and knowledge capacity worldwide."

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