CHINA REGULATORY

COSMETIC INGREDIENT REGISTRATION

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THE “RULES” TO MARKET IN CHINA

COMPLIFE’S PRACTICAL SUGGESTIONS

Thanks to the direct experience of our **Chinese team**, **Complife** presents a short guide with the **most important notions to market a cosmetic ingredient in China**.

Enjoy the reading and remember that among our services we can support you in all regulation consulting services about the NCI application and existing ingredients notification, including submission processes.

WHAT IS A **“NEW COSMETIC INGREDIENT”**?

THE NEW COSMETIC INGREDIENTS IS A NATURAL OR ARTIFICIAL INGREDIENT THAT IS FIRSTLY USED IN COSMETIC PRODUCTS IN CHINA.

- REGULATIONS ON THE SUPERVISION AND ADMINISTRATION OF COSMETICS, article 11

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WHEN IS AN INGREDIENT CONSIDERED A **NCI**?

INVENTORY OF EXISTING COSMETIC INGREDIENTS IN CHINA (IECIC):
The list of ingredients allowable to be used, and the determinant of new cosmetic ingredients.

- IF A INGREDIENT'S INCI NAME IS NOT IN THIS INVENTORY, IT WILL BE DETERMINED AS NCI IN CHINA.
- USE THE <IECIC 2021 VERSION> FOR NCI SELF CHECK.

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HOW TO CLASSIFY THE NCI

FOR DIFFERENT MANAGEMENT PROCEDURES?

China supervision authority classify the NCI based on the NCI safety assessment, different types of NCI will have different management.

1 IF THE NCI BELONGS TO

- PRESERVATIVE
- SUNSCREEN
- HAIR DYING
- ANTI-SPOT AGENT
- WHITING AGENT

→ IT WILL BE CLASSIFIED AS **"HIGH RISK"** INGREDIENTS SCOPE

2 ALL OTHER NCI BELONGS TO **ORDINARY INGREDIENTS**

! THE SCOPE OF **HIGH RISK INGREDIENTS IS DYNAMIC,** CHINA SUPERVISION AUTHORITY HAVE THE POWER TO ADJUST THE SCOPE BASED ON THE INGREDIENT'S SAFETY CONCERN.

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WHAT ABOUT THE REGISTRATION
OF INGREDIENTS ALREADY IN USE?

EXISTING INGREDIENTS SAFETY REPORT DON'T NEED TEST

you just need to prepare the safety information according to the ANNEX 14 and submit to the NMPA system,
the local responsible person for existing ingredients safety report is not necessary.

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HOW TO PROCEDE FOR A **NCI APPLICATION**?

DIFFERENT BETWEEN **HIGH RISK** OR **NOT HIGH RISK:**

1 HIGH RISK NCI SHALL REGISTER TO NMPA TO GET **APPROVAL BEFORE USE**

2 OTHERS SHALL JUST **FINISH RECORDAL FILING** PROCEDURE BEFORE USE

- After registration or recordal filing, only registrants or recordal filers can use this new ingredient.
- The users shall report the use and safety status within 3 years.
- If no safety concern within 3 years, the new ingredient shall be added into IECIC.

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REGISTRATION PROCEDURE

1

APPLY A NEW ACCOUNT FOR THE APPLICATION SYSTEM, BECAUSE FOR NCI APPLICATION BOTH OFFLINE APPLICATION AND ELECTRONIC PORTAL ARE NEEDED.

2

TEST, WHICH INCLUDE THE SAFETY TEST ITEMS AND THE EFFICACY TEST ITEMS.

3

PREPARE THE APPLICATION DOSSIER ACCORDING TO THE DOCUMENTS REQUIREMENT OF NCI APPLICATION.

4

SUBMIT BOTH PAPER DOSSIER AND ONLINE APPLICATION IN THE NCI APPLICATION SYSTEM TO CHINA NMPA.

5

THE NMPA WILL ORGANIZE THE EXPERT TO REVIEW THE DOSSIER.

IF THE EXPERT CONSIDERS THIS NCI FREE OF SAFETY CONCERN THROUGH THE REVIEW OF THE DOSSIER, NMPA WILL APPROVE THIS NCI AND WILL ANNOUNCE THE APPROVAL OF THIS NCI IN THE SPECIFIC GOVERNMENT WEBSITE.

6

AFTER ANNOUNCEMENT OF NCI PUBLISHED, THIS INGREDIENT WILL BE ENTERED INTO THE 3 YEARS OF SAFETY MONITORING OFFICIALLY.

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RECORDAL FILING PROCEDURE

The biggest difference vs. registration procedure is that the NCI recordal-filing procedure **doesn't have NMPA technical review step**.
After the NMPA acceptance center **received the NCI recordal-filing application**, they will **only check the dossier completeness.**
If the documents are complete the **NMPA will announce this NCI has already finished recordal-filing** in the government website directly.
This NCI is allowed to be **put on the market once this announcement has been made** and it will enter into the 3 years of safety monitoring period.

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SAFETY MONITORING PROCEDURE

In the **3 YEARS OF SAFETY MONITORING PERIOD**, the ingredient is still managed as NCI:
only **REGISTRANTS OR RECORDAL-FILERS COULD USE THE INGREDIENT** and they have responsibility to **monitor, evaluate and report** the use status and safety concern of the ingredient.

The cosmetic manufacturer who wants to put the ingredient in their final products needs to get authorization from registrants or recordal-filers and will assist the registrants or recordal-filers to collect the use condition of the NCI in the final products.

EVERY YEAR, the registrants or recordal-filers shall **REPORT THE SERIOUS COSMETIC ADVERSE REACTIONS** or mass adverse reactions in China or aboard, which are suspected to be caused by the use of this NCI or other similar ingredients that support the function of this ingredient and are restricted or prohibited or which standard use is adjusted in other countries.

The NMPA technical evaluation institution will evaluate the report to assess the ingredient's safety, if the ingredient is considered **NO SAFETY RISK AFTER 3 YEARS, it will be added into the IECIC**, managed as used ingredient and allowed to be used for all cosmetic enterprises.

!! PAY ATTENTION THAT THE 3 YEARS IS CALCULATED FROM THE PRODUCTION DATE OF THE FINAL PRODUCT'S THAT FIRST TIME USE THE NCI.

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FIRST TIME YOU PROCEED NCI REGISTRATION OR RECORDAL FILING IN CHINA?

APPLY A NEW ACCOUNT FOR THE NCI APPLICATION SYSTEM (which can also be used for safety test system).
2 government application systems for NCI registration and recordal filing – both online - the **account is common to both systems.**

SAFETY TEST APPLICATION SYSTEM procedure

- Choose the qualified test lab by NMPA in the system to supply the test service
- Fill in the NCI available test items in the system
- Final test reports will be upload in the system

→ http://jyxt.nmpa.gov.cn:8080/jyxt/

NCI APPLICATION SYSTEM procedure

- Submit the registration or recordal-filing documents in the system
- Monitor the review and approval status in the system
- Check expert review feedback in the system

→ https://zwfw.nmpa.gov.cn/web/index

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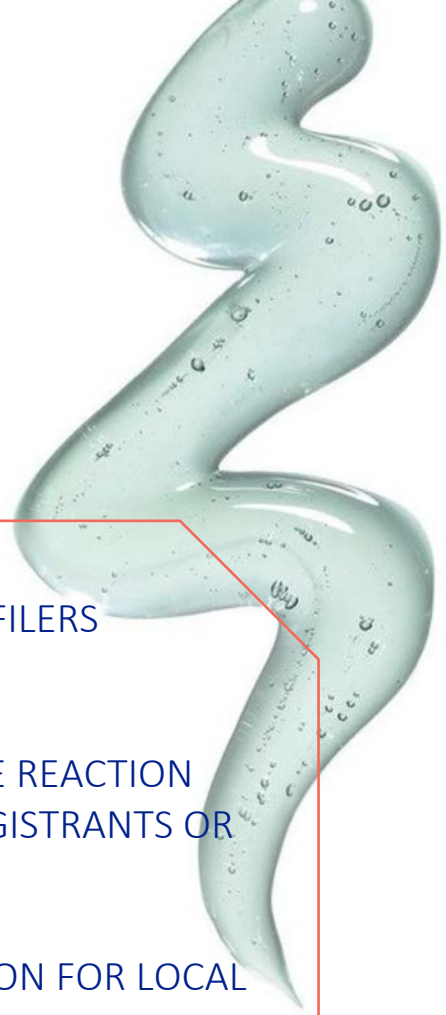
LOCAL OR FOREINGN?
2 PROCEDURES:



LOCAL

1. REGISTRANTS OR RECORDAL FILERS BASIC INFORMATION
2. THE SUMMARIZE OF ADVERSE REACTION MONITORING SYSTEM OF REGISTRANTS OR RECORDAL FILERS

FOREIGN

1. REGISTRANTS OR RECORDAL FILERS BASIC INFORMATION
2. THE SUMMARIZE OF ADVERSE REACTION MONITORING SYSTEM OF REGISTRANTS OR RECORDAL FILERS
3. THE LETTER OF AUTHORIZATION FOR LOCAL RESPONSIBLE AGENT
   (IF HAVE LOCAL RESPONSIBLE AGENT)
4. THE BASIC INFORMATION OF LOCAL RESPONSIBLE AGENT
   (IF HAVE LOCAL RESPONSIBLE AGENT)

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DOCUMENTS REQUIREMENT FOR NCI APPLICATION

1 NAME, ADDRESS AND CONTACT INFORMATION OF REGISTRANTS, RECORDAL FILERS AND RESPONSIBLE AGENT

2 THE RESEARCH REPORT

(Which contains: the research background, the basic information - name, source, composition, molecular weight, molecular formula, structure, physicochemical property etc., the use information - use specification in final product, function, use scope, safety dosage, shelf life, warning, use condition or approval condition in foreign cosmetic, the supporting data of the function).

3 MAKING PROCESS of NCI

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DOCUMENTS REQUIREMENT FOR NCI APPLICATION

4 QUALITY CONTROL STANDARD

(Which contains: stability data, quality specification and test method, potential risk substance and the control standard).

5 SAFETY EVALUATION DATA

(Which contains: toxicological safety evaluation data (toxicology test report), risk assessment data).

6 THE TECHNICAL STANDARD

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TOXICOLOGY TEST ITEMS FOR NCI APPLICATION

CLASS 1

The new cosmetic ingredients which **FIRST USE AS** sunscreen, preservative, colorant, hair dying, anti-spot agent, whitening agent, anti-hair loss agent, anti-acne agent, anti-wrinkle agent, anti-dandruff agent, deodorization agent in the final product, and others have high biological activity, which first use in the final product.

CLASS 2

The new cosmetic ingredients which **FIRST USE NOT AS** sunscreen, preservative, colorant, hair dying, anti-spot agent, whitening agent, anti-hair loss agent, anti-acne agent, anti-wrinkle agent, anti-dandruff agent, deodorization agent in the final product.

CLASS 3

The new cosmetic ingredients that **DON'T HAVE FUNCTION LISTED** in "class 1", and have fully evidence to prove this raw material have 3-year safety use history in foreign country.

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TOXICOLOGY TEST ITEMS FOR NCI APPLICATION

CLASS 4

The new cosmetic ingredients have function listed in “class 1”, have fully evidence to prove this raw material have **3-YEAR SAFETY USE HISTORY** in foreign country.

CLASS 5

The new cosmetic ingredients which have **SAFETY EDIBLE HISTORY.**

CLASS 6

THE POLYMER with an average molecular weight greater than 1000 daltons, containing less than 10% oligomer, stable in structure and properties (except high biological activity).

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TEST ITEM	CLASS 1	CLASS 2	CLASS 3	CLASS 4	CLASS 5	CLASS 6
Acute oral and percutaneous tests*	+	+	+/-	+		
Skin and eye irritation/corrosion test	+	+	+	+	+	+
Skin allergy test	+	+	+	+	+	
Skin phototoxicity test**	+/-	+/-	+/-	+/-	+/-	+/-
Skin photoallergy test**	+/-	+/-	+/-	+/-	+/-	
Mutagenesis test	+	+	+	+		
Repeated dose oral or transdermal toxicity test	+	+		+		
Teratogenic test	+					
Chronic toxicity/carcinogenicity combination test	+					
Inhalation toxicity test***	+/-	+/-	+/-	+/-	+/-	+/-

** For class 3, this test could be exempted, if supply the safety report issued by international authoritative certification institute or have human use safety report.*
*** If the raw material have ultraviolet absorption function.*
**** If the raw material is possible to be exposed by inhalation*

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ADDITIONAL REQUIREMENT FOR ANIMAL SUBSTITUTION EXPERIMENT

THE USE OF **ALTERNATIVE METHODS INSTEAD OF ANIMAL TESTS** ARE ACCEPTED UNDER **SPECIFIC CONSIDERATIONS**:

1. This alternative method shall be already included by international authoritative alternative test method verification institutions.

2. The evidence proving that this method is consistent with results obtained from the traditional toxicological test method in <China Safety and Technical Standards for Cosmetic> (STSC), which includes:
    - a brief introduction to the study process of this alternative test method and the study data;
    - result analysis and conclusions of no less than 10 known toxic subjects.

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ALTERNATIVE METHODS APPROVED BY NMPA UP TO NOW

Below are alternative methods that do not involve live animals approved by NMPA up to now. They are all applied to NCI registration/recordal-filing, but only accepted based on Integrated Approaches to Testing and Assessment (IATA) strategies.

No.	TEST ITEM	APPROVED ALTERNATIVE METHOD
18	Phototoxicity	In Vitro 3T3 NRU Phototoxicity Test
21	Eye irritation	Short Time Exposure In Vitro Test Method(STE)
24	Skin Sensitization	In Chemico Skin Sensitisation: Direct Peptide Reactivity Assay (DPRA)
25	Mutagenicy	In Vitro Mammamlian Cells Micronucleus Test

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TO KEEP IN MIND:

RESPONSIBLE PERSON IN CHINA

For new cosmetic ingredients **registration**, the **Chinese local responsible person is a mandatory requirement.**
For existing ingredients **safety report**, the Chinese local responsible person is **not necessary**, as long as the reporter could use the Chinese application system.

WHO IS RESPONSIBLE FOR THE REGISTRATION

The responsible **for the NCI application** is the **raw material enterprise** who put the new ingredient on the China market.
The responsible of the NCI application shall take responsibility for the NCI registration or recordal-filer and the **foreign responsible shall authorize** one **domestic responsible person in China** to handle the NCI registration or recordal-filer affairs.

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RAW MATERIAL DATABASE (ACTIVE NOW)

The system for existing ingredients safety information collection is running.
Some ingredients manufacturer already began to report their ingredient's safety information.
LINK HERE: https://zwfw.nmpa.gov.cn/web/index

The NMPA established a transition period for existing ingredients safety information collection that is:

- **From May 1st 2022**, the existing ingredients which have quality specifications in the *China Safety and Technical Standards for Cosmetic* shall submit completed safety information according to Annex 14;
- From **Jan 1st 2023**, the existing ingredients which belongs to **preservative, sunscreen, colorant, hair dying, anti-spot agent, whitening agent** shall begin to submit completed safety information according to Annex 14;
- From **Jan 1st 2023**, also **other existing ingredients** shall begin to submit completed safety information according to Annex 14.

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