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Case History notifica al portale NMPA delle materie prime

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Contesto normativo - CSAR

1989

Cosmetic Hygiene Supervision Regulations (CHSR)

01.2021

Cosmetic Supervision and Administration Regulation (CSAR)

- Semplificare il processo di approvazione per ingredienti (low risk)
- Promuovere l'innovazione nell'industria cosmetica
- Post-market surveillance

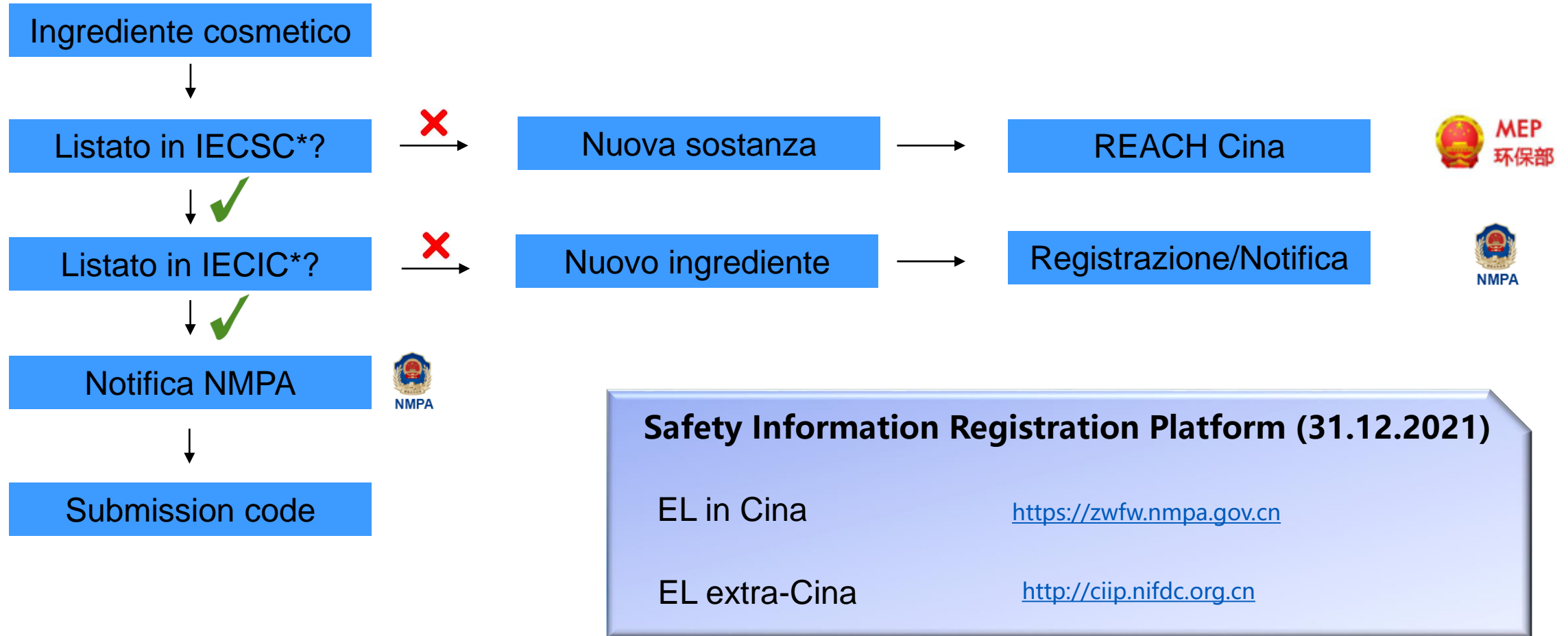


**Administrative Measure on
Cosmetic Registration and
Filing**

**Supervision and
Administration Measure on
Cosmetics Manufacture and
Operation**

**Technical Guidelines for
Cosmetic Safety Assessment**

CSAR - Safety Information Registration Platform



IECSC*: Inventory of Existing Chemical Substances in China

IECIC*: Inventory of Existing Cosmetic Ingredients in China

Notifica NMPA – Allegato 13



*si riferisce all'impresa responsabile della sicurezza della materia prima, che può essere l'effettiva impresa di produzione della materia prima o l'impresa affiliata che appartiene alla stessa società del gruppo

“Technical Guidance for Submission of Cosmetic Ingredient Safety Information”
Provisions for Management of Cosmetic Registration and Notification Dossiers – Allegato 12

Produttore di materie prime o EL autorizzata presenta **Allegato 13** (Enterprise Information Form)¹ insieme a :

- Business licence del produttore;
- POA (procura) rilasciata dal produttore (nel caso di autorizzazione ad un EL nazionale);

tutta la documentazione deve essere fornita in lingua cinese


Enterprise Information Form (Annex 13)	
Raw Materials Manufacturer Name	! Coerenza con tutta la documentazione del produttore
Country	<input type="checkbox"/> International <input type="checkbox"/> domestic
address of manufacturing site	
The name of the authorized domestic enterprise	Fill in if there is an authorization, with attached Letter of Authorization
The address of the authorized domestic enterprise	Fill in if there is an authorization, with attached Letter of Authorization
Contact Info	Contact
	Mobile Phone:
	Tel:
	E-mail:
	The actual office address
Post Code	

A Letter of Commitment (...)	
Company seal of ingredient manufacturer or authorized enterprise filling out this form	

¹Provisions for Management of Cosmetic Registration and Notification Dossiers

Notifica NMPA – Allegato 14 (I)

- ❖ scelta volontaria del produttore di materie prime
- ❖ facilitare processo di registrazione/notifica del produttore di cosmetico finito – info sulla sicurezza dell'ingrediente
- ❖ Informazioni presenti nella documentazione standard dell'ingrediente (TDS, SDS, COA)

Information Related to Ingredients Safety (Annex 14)					
Trade name of ingredient	 Coerenza con la documentazione standard del prodotto				
Composition of ingredient (including compound components)	Chinese name of the component (IECIC): 1. 2. 3. ...	INCI Name (English)	Remarks: Ingredien ti nano – «nano- level»; ing. miscele di origine petrolchi mica – CAS#	Concentration:	
				Range	Typical/ target value For a compound /mixed ingredient produced by other reasons

- Evitare marchi commerciali TM o [®]
- INCI breakdown - ingredienti intenzionalmente aggiunti
- Impurezze, se di interesse (STSC¹), listate nella sezione *Risk substance*
- Valore tipico: può essere un valore teorico o un valore medio o un valore rappresentativo

¹Safety and Technical Standard for Cosmetics

Notifica NMPA – Allegato 14

Basic properties of raw materials properties	
<p>a. Basic characteristics of major components</p> <ul style="list-style-type: none"> <input type="checkbox"/> Single compound with clear structure <input type="checkbox"/> Polymer/ mixture (referring to a mixture that contains polymers) <input type="checkbox"/> Other mixture 	<p>d. Other characteristics</p> <ul style="list-style-type: none"> <input type="checkbox"/> Peptides <input type="checkbox"/> Proteins <input type="checkbox"/> Nano ingredients <input type="checkbox"/> Fragrances
<p>b. Source of ingredient (multiple choices available)</p> <ul style="list-style-type: none"> <input type="checkbox"/> Synthesis <input type="checkbox"/> Plants (direct source) <input type="checkbox"/> Plants (indirect source) <input type="checkbox"/> Animals (direct source) <input type="checkbox"/> Animals (indirect source) <input type="checkbox"/> Algae and macrofungi (direct source) <input type="checkbox"/> Algae and macrofungi (indirect source) <input type="checkbox"/> Bacteria, fungi or other unicellular organisms <input type="checkbox"/> Minerals <input type="checkbox"/> Others 	<p>e. Compound/mixed ingredient</p> <ul style="list-style-type: none"> <input type="checkbox"/> A mixture produced by the synthesis process, etc. <input type="checkbox"/> Mixed extraction <input type="checkbox"/> Only addition of stabilizers, preservatives, antioxidants and other components that ensure the quality of the ingredient <input type="checkbox"/> Only addition of necessary solvents and stabilizers, preservatives, antioxidants and other components that ensure the quality of the ingredient <input type="checkbox"/> Others
<p>c. Production methods of ingredient (multiple choices available)</p> <ul style="list-style-type: none"> <input type="checkbox"/> Naturally existing <input type="checkbox"/> Chemical synthesis <input type="checkbox"/> Only physical <input type="checkbox"/> Only physical mixing <input type="checkbox"/> Solvent extraction <input type="checkbox"/> Hydrolysis <input type="checkbox"/> Fermentation using genetic engineering technology or cell/tissue culture <input type="checkbox"/> Other general fermentation or cell/tissue culture <input type="checkbox"/> Others 	

- direct source = processi fisici
- Mixed extraction : miscela di diverse biomasse prima dell'estrazione

Notifica NMPA – Allegato 14

Information Related to Ingredients Safety (Annex 14)					
Trade name of ingredient	PLUMP Oléoactif				
Composition of ingredient (including compound components)	Chinese name of the component (IECIC):	INCI Name (English)		Range%	
	1. 霍霍巴 (SIMMONDSIA CHINENSIS) 籽油	1. Simmondsia Chinensis (Jojoba) Seed Oil		66-70	
	2. 石榴 (PUNICA GRANATUM) 花提取物	2. Punica Granatum Flower Extract		18-22	
	3. 聚甘油-3 二异硬脂酸酯	3. Polyglyceryl-3 diisostearate		10-14	
Basic properties of raw materials properties	a. Basic characteristics of major components <input checked="" type="checkbox"/> Polymer/ mixture	b. Source of ingredient <input checked="" type="checkbox"/> Plants (direct source) <input checked="" type="checkbox"/> Plants (indirect source)	c. Production methods of ingredient <input checked="" type="checkbox"/> Solvent extraction	d. Other characteristics <input checked="" type="checkbox"/> N/A	e. Compound/ mixed ingredient <input checked="" type="checkbox"/> Others

Notifica NMPA – Allegato 14

Recommended addition amount in cosmetics (non-mandatory)	Leave-on cosmetics (%)	
	Rinse-off cosmetics (%)	
Other restrictions on use (non-mandatory)	Formula taboo Other restrictions on use Warning words	
Ingredient characters	Color	
	Odor	
	State	
Description of physicochemical properties	Solubility (mandatory)	<input type="checkbox"/> Water-soluble <input type="checkbox"/> Fat-soluble <input type="checkbox"/> Insoluble <input type="checkbox"/> Others
	Other properties	
Brief Description of Process :		
<input type="checkbox"/> Plants (direct source) <input type="checkbox"/> Animals (direct source) <input type="checkbox"/> Algae and macrofungi (direct source)	Latin name of starting material Part(s) used	

- Se disponibili dati da parte del produttore di materie prime
- Per sostanze regolamentate riportare la % raccomandata
- Informazioni chimico-fisiche riportate nella Scheda Tecnica del prodotto
- Descrizione del processo in accordo alla documentazione tecnica fornita – flow chart

Notifica NMPA – Allegato 14

Information Related to Ingredients Safety (Annex 14)			
Trade name of ingredient	PLUMP Oléoactif		
Recommended addition amount in cosmetics (non-mandatory)	2 – 5%		
Other restrictions on use (non-mandatory)	N/A		
Ingredient characters	Color: from light yellow to amber		
	Odor: sweet, fatty, flowery		
	State: liquid		
Description of physicochemical properties	<table border="0"> <tr> <td>Solubility (mandatory)</td> <td> <input type="checkbox"/> Water-soluble <input checked="" type="checkbox"/> Fat-soluble <input type="checkbox"/> Insoluble <input type="checkbox"/> Others </td> </tr> </table>	Solubility (mandatory)	<input type="checkbox"/> Water-soluble <input checked="" type="checkbox"/> Fat-soluble <input type="checkbox"/> Insoluble <input type="checkbox"/> Others
	Solubility (mandatory)	<input type="checkbox"/> Water-soluble <input checked="" type="checkbox"/> Fat-soluble <input type="checkbox"/> Insoluble <input type="checkbox"/> Others	
Other properties: Peroxide value: ≤ 15,0 meqO ₂ /kg; Relative density at 20°C: 0,850-0,910			
Brief Description of Process :			
<p>Grinding and cryo-grinding of vegetable biomass of pomegranate flowers. Oily extraction using jojoba oil as solvent and polyglyceryl-3-diisostearate as co-extractant.</p> <p>1.Punica Granatum Flower Extract Latin name: Punica Granatum Part used: flower</p> <p>2.Simmondsia Chinensis (Jojoba) Seed Oil Latin name: Simmondsia Chinensis Part used: seed</p>			

Notifica NMPA – Allegato 14 (II)

Ingredient quality and characteristic indicators					
Serial No.	Indicators	Molecular formula	CAS No.	Control range	Testing methods
<p>(For a single ingredient with a clear chemical structure, purity requirements shall be provided) (For polymer ingredients, the degree of polymerization and average molecular weight shall be provided) (For oligopeptides, peptides and protein ingredients, the amino acid sequence shall also be specified) (For an ingredient with unclear chemical structure, quantitative requirements for index components or total components, evaporation residue/solid content, loss on drying/water, residue on ignition, etc. shall be provided)</p>					

- Informazioni in TDS e CoA
- Sostanze caratterizzanti la materia prima

Information Related to Ingredients Safety (Annex 14)					
Trade name of ingredient		PLUMP Oléoactif			
Serial No.	Indicators	Molecular formula	CAS No.	Control range	Testing methods
1	Total phenols eq. Oleuropein	C ₂₅ H ₃₂ O ₁₃	32619-42-4	≥ 2000 ppm	internal method
2	Polymerization degree	N/A	N/A	~ 3	N/A
3	Average molecular weight	N/A	N/A	~ 773 Da	N/A

Notifica NMPPA – Allegato 14 (III)

III. Risk Information and Control Indicators	
Heavy metal indicators: (if applicable)	drop-down menu: Lead (Pb)/Arsenic (As)/Mercury (Hg)/Cadmium (Cd)/Chromium (Cr)/Nickel (Ni)/Selenium (Se)/Beryllium (Be)/Stibium (Sb)/Strontium (Sr)/Zirconium (Zr)/Cobalt (Co)/Others (editable after choice)
Pesticide residue	
Microbiological risk	drop-down menu: Aerobic plate count/Total mold and yeast/Thermotolerant coliforms/Staphylococcus aureus/Pseudomonas aeruginosa/Others (editable after choice)
Other risks	drop-down menu: Methanol/Dioxane/Asbestos/Formaldehyde/Diglycol/Phenol/Acrylamid e/Secondary alkylamine/Nitrosamine/1,3-Butadiene/Hydroquinone/Benzene/Others (editable after choice)

- Sostanze e limiti definiti nel Safety and Technical Standard for Cosmetics (STSC)
- Pesticidi residui solo per ingredienti derivazione vegetale

Information Related to Ingredients Safety (Annex 14)					
Trade name of ingredient		PLUMP Oléoactif			
	risk substance name	Limit requirements		risk substance name	Limit requirements
Heavy metal indicators: (if applicable)	Arsenic	< 0.01 ppm	Microbiological risk	Mesophilic aerobic counts	< 100 CFU/g
	Cadmium	< 0.01 ppm		Staphylococcus	absent
	Mercury	< 0.01 ppm		Pseudomonas aeruginosa	absent
	Lead	< 0.01 ppm		Candida albicans	absent
Pesticides residues		< 1 ppm		Escherichia coli	absent

Notifica NMPA – Allegato 14 (IV - V - VI)

IV. Evaluation Conclusions from International Authoritative Institutions (Optional)			
Evaluation institution SCCS/ CIR/ IFRA/ WHO/ FAO	Evaluation amount or safety limit	Restriction conditions	Evaluation report
V. Brief Description of Use Requirements in Other Industries (Optional)			
VI. Other Issues to Be Stated (Optional)			

Information Related to Ingredients Safety (Annex 14)				
Trade name of ingredient		PLUMP Oléoactif		
Chinese Name	Assessment institution	Evaluation amount or safety limit	Restriction conditions	Evaluation report
Simmondsia Chinensis (Jojoba) Seed Oil	CIR	100 %	Total	Uploaded CIR report
Polyglyceryl-3 diisostearate	CIR	39 %	Leave-on	Uploaded CIR report
		29,7 %	Rinse-off	

Codice di notifica e Comunicazione a valle

PLUMP Oléoactif **118598** – **01580** – **6103**

ingredient code

manufacturer code

quality specification code

- Info necessarie da comunicare al produttore di PF:
Codice, nome commerciale dell'ingrediente, nome del fornitore come da Allegato 13 e composizione dell'ingrediente
- Collaborare con il produttore di PF per fornire ulteriori informazioni sulla sicurezza dell'ingrediente
- Ogni modifica all'Allegato 14 genera un nuovo codice da comunicare al produttore di PF
- Portale NMPA : nome commerciale, nome del produttore e codice dell'ingrediente (no Allegato 14)
- Cambio della EL autorizzata da produttore estero non determina la perdita del codice. Sarà necessario inviare un nuovo Allegato 13
- Se il codice di notifica non è disponibile è possibile fornire al produttore di PF l' allegato 14 compilato con le info disponibili nella documentazione standard
- Per ingredienti con stesso nome commerciale (es. RSPO) e/o INCI name è necessario effettuare la notifica per ogni ingrediente

化妆品原料安全信息

原料报送码: 118598-01580-6103

【一、基本信息和工艺简述】

原料商品名*	PLUMP Oléoactif				含量	
	序号	中文名称	INCI 名称/ 英文名称	备注	典型值/目 标值	范围
原料组成*	1	霍霍巴 (SIMMONDSIA CHINENSIS) 籽油	SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL			66-70%
	2	石榴 (PUNICA GRANATUM) 花提取物	PUNICA GRANATUM FLOWER EXTRACT			18-22%
	3	聚甘油-3 二异硬脂酸 酯	POLYGLYCER YL-3 DIISOSTEARA TE			10-14%

Thank You

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