

Cosmetic regulatory updates from Saudi Arabia and the United Arab Emirates

Catherine APOLINARIO – Cosmed – 13/10/20210

REGULATORY CONTEXT





The Cooperation Council for the Arab States of the Gulf (GCC) :

- Bahrain.
- Kuwait.
- Oman.
- Qatar.
- Saudi Arabia.
- United Arab Emirates.



- Led by: SFDA (Saudi Arabia), ESMA (UAE), GSO (GCC)

هيئة التقييس

لدول مجلس التعاون لدول الخليج العربية
GCC Standardization Organization



هيئة الإمارات للمواصفات والمقاييس
Emirates Authority For Standardization & Metrology

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority



UNITED ARAB EMIRATES
MINISTRY OF INDUSTRY
& ADVANCED TECHNOLOGY

Harmonized standards in the GCC:

- GSO 1943/2016
 - **In line with EU regulations**
 - **UPDATE 2021 (July 2021)**
- GSO 2528/2016 on cosmetic claims

Country specifications:

- Saudi Arabia: updates for controlled substances
- Separate system for registration
- Oman, Qatar > Specific standards (+ GSO 1943/2016)

GSO 1943:2016

لائحة فنية خليجية

متطلبات السلامة في مستحضرات التجميل والعناية الشخصية

Gulf Technical Regulation

Safety Requirements of Cosmetics and Personal Care Products



DEFINITION & CLASSIFICATION

Definition

Any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors.

6 main functions or purpose :

- To clean
- To perfume
- To change the appearance
- To protect
- To keep in good condition
- To correct body odors

Field of application :

- The epidermis
- The hair system
- The nails
- The lips
- The teeth
- The mucous membranes of the oral cavity
- The external genital organs
- Mucous membranes :
 - In the vicinity of the eyes
 - On the lips
 - In the oral cavity
 - On the external genital organs

REGISTRATION



UAE

ECAS Certificate of Conformity

- Certificate issued by a Notified Body (Intertek, SGS etc...)
- ESMA: Emirates Authority for Standardization & Metrology
- Valid for 1 year
- Issued in the name of a UAE-based company



UNITED ARAB EMIRATES
MINISTRY OF INDUSTRY
& ADVANCED TECHNOLOGY

Dubai Emirate (**Double registration**)



- Registration (on MONTAJI portal)
- Local regulations
- Dubai Municipality
- Valid for 5 years

SAUDI ARABIA

- Market access:
 - Obtaining a **Certificate of Conformity (CoC)**, issued by a body approved by SFDA (Intertek, SGS, Cotecna etc...)
 - Product **notification** on the eCosma portal
 - Compliance with **GSO 1943/2016**
 - **Custom clearance and CoC : new platform FASEH**



الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Login with ecosma

Login to your account

Clearance Services System

An electronic system provided by the Food and Drug General Authority that enables the importer to submit a release request for food and drug products, .medical devices, cosmetics, and imported fodder

	For Imported products	For local products
Who?	Importer	Local manufacturer
Required document	Letter of authorization to register the products Product image (clear and legible) including primary and secondary labeling Qualitative-quantitative composition*	Product image (clear and legible) including primary and secondary labeling Qualitative-quantitative composition*
Responsibilities of Notifying Person?	<p>Safety of product</p> <p>Notify SFDA if any adverse effect or recall happened</p> <p>Keep PIF</p> <p>Notify SFDA if any amendment or update regarding the product</p> <p>Sales records</p>	
Time needed?	15 days from submitting a complete request	
Registration step	<ol style="list-style-type: none"> 1. Create account 2. license warehouse 3. Notify external manufacture 4. Product notification 5. Custom clearance certificate 	
Product Types?	<ol style="list-style-type: none"> 1. Simple product (1 product = 1 notification) ex: cream, shampoo etc... 2. Simple products with variants (a product with different colours) Ex: lipstick 3. Composite products (1 product set of different colours = 1 notification) Ex: eye shadow pallet 4. Kit (many produced marketed in one kit = 1 notification) Ex : hair dye 	

Documents required	UAE	KSA
List of ingredients	X	X
Artwork of the packaging (primary, secondary + notice)	X	X
Certificate of analysis (specifications) Test report issued by an ISO 17025 accredited laboratory	X	X
Cosmetic Product Safety Report	X	X
GMP certificate	X	X
manufacturer information		X
Free Sale Certificate	X	X
Distribution agreement		X
Commercial license	X	X
Warehouse Licence		X

CONTROLLED SUBSTANCES



- Same lists as in Europe (ban – restricted – colorants – preservatives and UV filters)
- **Big difference from one country to another:**
 - **UAE:** on the version of the GSO 1943 standard published in 2016
 - **KSA:** country-specific list: very regular amendments. The last one concerns titanium dioxide.
 - **Other countries:** standard system with + or - additional substances (impurities)



LABELLING & CLAIMS



On the **primary and secondary** pack:

- **Product name ***
- **Product function ***
- Manufacturer's name / Brand
- Address of the manufacturer or distributor
- Production date or batch number
- date of minimum durability (Best before date or PAO)
- Weight/volume
- Country of origin
- List of ingredients (INCI)
- **Instructions for use & storage if necessary ***
- **Precautions/warnings ***

(* **markings** required in Arabic and English / the others can be in English and/or arabic)




6 Common criteria as in Europe :

- Legal Compliance,
 - Truthfulness,
 - Evidential Support,
 - Honesty,
 - Fairness,
 - Informed Decision-Making
-
- + Examples of Unacceptable Claims
-
- Halal not mandatory

Products category	Examples of Unacceptable Claims	Notes
Skin care product	Makes skin younger يجعل الجلد أكثر شباباً	<p>In general release the name of “Anti-aging cream” or “Anti-wrinkle cream” is not a problem as it is a description of the product, provided that they meet the following conditions:</p> <p>1- The name must wrinkles and s example, Anti-aging/Anti-Wrinkle products,</p> <p>But, the Anti-aging/Anti-Wrinkle <u>effect</u> The products.</p> <p>2- Does not accept the presence of an cosmetically acc definition-, for ex more youthful, re appearance of wri</p>
	Reduces aging يبطئ الشيخوخة أو التقدم في السن	
	Reverses aging يصاد التقدم في السن	
	Slows aging يبطئ التقدم في السن / يؤخر الشيخوخة	
	Prevents aging يمنع التقدم في السن	
	Eliminates aging يقضي على التقدم في السن	
	Stops aging يوقف التقدم في السن	
	Reverses aging إعادة الشباب	

ينهي القشرة	ingredient; while the claim cosmetic products. - A product “preventing hair loss” is not a cosmetic product.
Stimulates hair follicles	
ينشط بصيالات الشعر	
Alopecia	
الصلع	
Prevents/treats alopecia	
يمنع/يعالج الصلع	
Prevents hair loss	
يمنع تساقط الشعر	
Replace thinning hair	
استبدال الشعر الرقيق	
Restore hair cells	
استعادة خلايا الشعر	
Any reference to effect on physiological growth of hair	
أي إشارة للتأثير على النمو الفسيولوجي الشعر	
Stimulates hair growth	
ينشط نمو الشعر	
Root penetrating (i.e. any action under the scalp)	
اختراق جذور الشعر (أي تأثير تحت فروة الرأس)	
Any reference to head lice	
أي إشارة إلى القمل	

SAFETY & PIF

- 
- Safe for human health when used under normal or reasonably foreseeable conditions of use
 - Completely free from pork and all its derivatives
 - Free from any filthy or decomposed substance
 - Should not contain graphics or images or phrases that are inconsistent with Islamic traditions
 - Compliance with good manufacturing practice (GSO ISO 22716)
 - **PIF :**
 - KSA : A product information file (PIF) is required for certification (CoC)
 - UAE : PIF is mandatory but only part B can be required by the authorities during an inspection



Test parameters according to GSO 1943

- Lead: 10 ppm
- Arsenic: 3 ppm
- Cadmium: 3 ppm
- Mercury: 3 ppm
- Antimony: 5 ppm
- 1,4-Dioxane: 10 ppm
- $4 < \text{pH} < 8$
- Microbiological limits (GSO ISO 17516 “Microbiology--Microbiological limits”)

Test by product category (valid for 1 year)

- Shampoos: microbiology, heavy metals, 1,4 dioxane
- Hair products: microbiology, heavy metals, 1,4 dioxane / formaldehyde
- Perfumes: heavy metals, allergens, flash point
- Whitening creams: microbiology, heavy metals, pH, hydroquinone
- ...



Thank you for your attention