

3rd Club

Friday 21 February 2025



Club Founder
Dr. Mahmoud Bahgat



Regulatory Affairs Club

**Understanding Cosmetic Products
Compliance and Registration**

Online Zoom

7 pm Egypt - 8 pm KSA - 9 pm UAE



Dr. Ahmed Salah
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Ex-EDA



Co-Founder & Host:
Dr. Zeyad Anany





Cosmetic Products Compliance & Registration In Egypt

Presented By

Dr. Ahmed Salah



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1. Introduction To Cosmetic Product Registration

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Why Cosmetic Product Registration is Easier and More Advantageous for Companies

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Registering cosmetic products offers several advantages compared to registering pharmaceutical products. Here are the key reasons why it is the better choice for companies:



- **1-Lower Cost** :Cosmetic product registration is generally more affordable than pharmaceutical registration, reducing financial burdens on businesses.
- **2-Faster Process** – The approval timeline for cosmetics is typically shorter, allowing companies to launch products more quickly.
- **3-Higher Profit Margins** – Cosmetic products often have higher markup potential compared to pharmaceutical products, increasing business profitability.
- **4-Easier Regulatory Requirements** – Cosmetic regulations are usually less strict than pharmaceutical regulations, simplifying the registration process.

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- **5-Flexible Formulations** – Cosmetic regulations allow for more flexibility in ingredients and formulations compared to medical products
- **6-Easier Market Entry** – Registered cosmetics can be sold in multiple regions with fewer restrictions than pharmaceutical products
- **7-Higher Consumer Demand** – The cosmetic industry is constantly growing, offering more opportunities for business expansion. These factors make cosmetic product registration a more efficient and profitable

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❑ Cosmetic Product Definition



- The Cosmetic Regulation defines "cosmetic product" as "any substance or mixture intended to be placed in contact with the various 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 and/or correcting body odors and/or protecting them or keeping them in good condition." This definition is thus based on two cumulative aspects: the site of application (placing on body/teeth/mucous membranes) and the "intended main (cosmetic) function" (i.e. cleaning, perfuming, changing appearance, protecting, keeping in good condition).



- **Cosmetics Regulation clarifies that “if the substance or mixture intended to be ingested, inhaled, injected or implanted into the human body shall not be considered to be a cosmetic product**
- **A product which presents itself as antiseptic and antibacterial products for the treatment or prevention of infection of the skin shall not be considered to be a cosmetic product**
- **The Cosmetics Regulation allows for secondary antibacterial claims in oral hygiene products or deodorants where the primary purpose is of a cosmetic nature**

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- **The assessment of whether a product is a cosmetic product has to be made on the basis of a case-by-case assessment, taking into account all characteristics of the product, including, for example, absorption, concentration, route of administration, frequency of application, application site, and the degree of penetration.**

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2. Cosmetic Product Categories



- a) **‘Rinse-off product’** means a cosmetic product which is intended to be removed after application on the skin, the hair or the mucous membranes;
- B) **‘Leave-on product’** means a cosmetic product which is intended to stay in prolonged contact with the skin, the hair or the mucous membranes;
- C) **‘Hair product’** means a cosmetic product which is intended to be applied on the hair of head or face, except eye lashes;
- (D) **‘Skin product’** means a cosmetic product which is intended to be applied on the skin;
- E) **‘Lip product’** means a cosmetic product which is intended to be applied on the lips;
- F) **‘Face product’** means a cosmetic product which is intended to be applied on the skin of the face;



Cosmetic Product Categories



- G) 'Nail product' means a cosmetic product which is intended to be applied on nails;
- H) 'Oral product' means a cosmetic product which is intended to be applied on teeth or the mucous membranes of the oral cavity;
- I) 'Product applied on mucous membranes' means a cosmetic product which is intended to be applied on the mucous membranes — of the oral cavity— or of the external genital organs;
- J) 'Eye product' means a cosmetic product which is intended to be applied in the vicinity of the eyes;
- K) 'Professional use' means the application and use of cosmetic products by persons in the exercise of their professional activity.

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3. Types Of Cosmetic Registration Licenses



- 1-Local
- 2-F/Toll
- 3-Toll
- 4-Imported from referenced country
- 5-Imported from non referenced country
- 6-Bulk imported referenced
- 7-Bulk imported non referenced
- 8-Under License referenced
- 9-Under License non referenced

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4. Registration Requirements According To EDA Regulatory Guide

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1-Requirements for Registering Companies in the Electronic Register for Cosmetics Companies



The company must create an account on the Electronic Company Profile of the pharmaceutical information system at the Egyptian Drug Authority and obtain the user's name and password of its account.

1. Authorization Letter: from the company to the representative
2. Personal ID : for the authorized company representative.
3. Factory License: (in case of cosmetic extract manufacturers).
4. Authorization Letter : (in case of agents)

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Requirements for Registering Companies in the Electronic Register for Cosmetics Companies



5. Commercial Register: indicating the company's business activity (whether toll manufacturing, importing, exporting, or Establishment and operation of a factory).
6. Tax Card
7. Official Receipt
8. Email Confirmation
9. Official Company Letter

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2-Documents Required for Cosmetics Registration



- The product trade name.
- Composition
- Artwork
- The shelf life of the product.
- A free sale certificate from the country of origin, in the case of imported cosmetic products It shall be submitted only in the case of seeking recourse of circulation reference

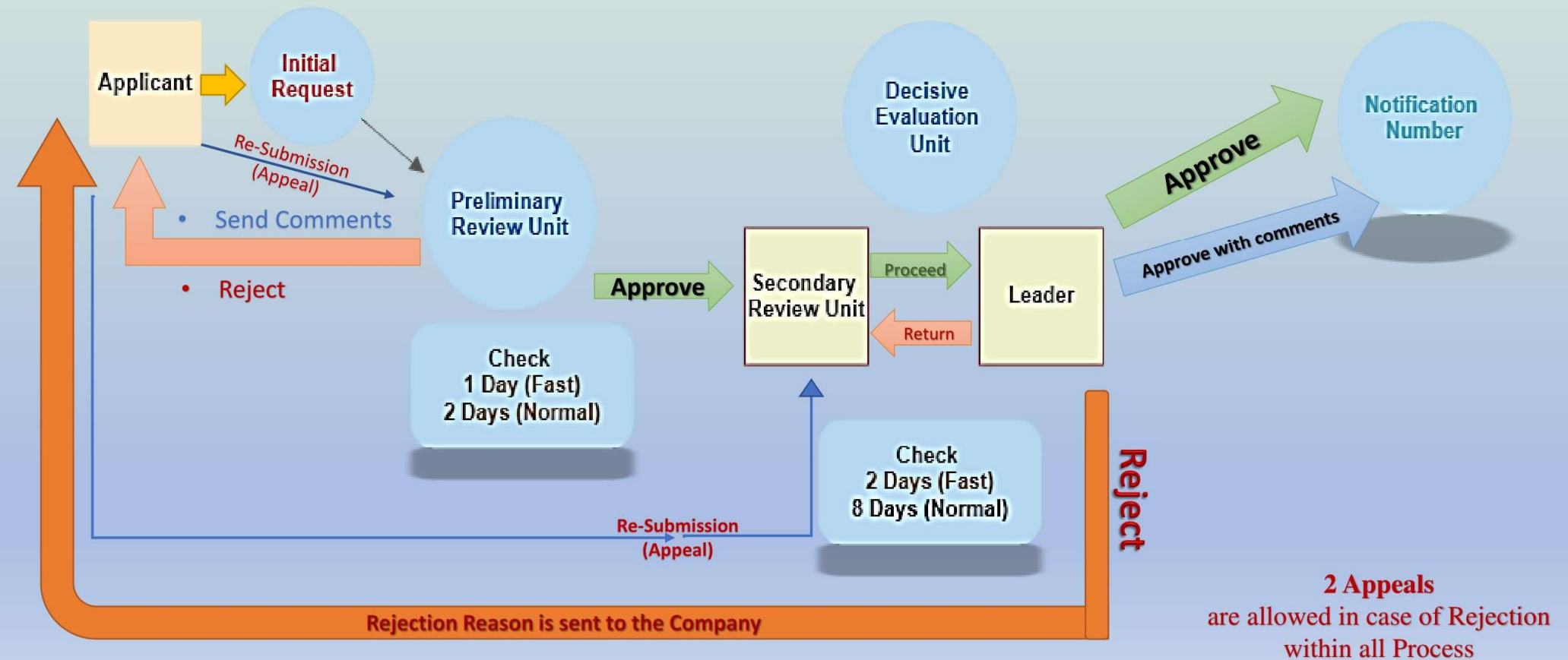
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- Factory license (TOLL, F-Toll, Local, Underlicense)
- Manufacturing Contract (Toll, F-Toll, Toll Underlicense)
- Letter of Authorization (Imported, Underlicense, Bulk)
- scientific reference, In the case of the claims mentioned on the outer package
- A payment receipt of fees

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Cosmetics Notification





5. Essential Artwork Data & Common Criteria Of Claims

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Illustrative information of the product artwork



- **1- Product Name**
- **2- Purpose of use**
- **3- Full Ingredients**
- **4- How to use**
- **5- Warnings & storage conditions**
- **6- Country of origin**
- **7- Applicant Company and manufacturer name**
- **8- Volume**
- **9- EDA Notification No**

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Common Criteria Of Claims



- It is important to ensure that the information conveyed to them through such claims is useful, understandable and reliable, and that it enables them to take informed decisions and to choose the products that best suit their needs and expectations
- 1-Claims for cosmetic products, shall be supported by adequate and verifiable evidence
 - 2-If it is claimed on the product that it contains a specific ingredient, the ingredient shall be deliberately present

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Common Criteria of claims



3-A claim extrapolating ingredient properties to the finished product shall be supported by adequate and verifiable evidence, such as by demonstrating the presence of the ingredient at an effective concentration

4-Claims for cosmetic products shall be objective and shall not denigrate the competitors, nor shall they denigrate ingredients legally used.

5-Therapeutic claim not allowed

6- Claims that it is free of actually banned ingredients are not allowed

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Common Criteria of claims



7-The level of evidence or substantiation shall be consistent with the type of claim being made, in particular for claims where lack of efficacy may cause a safety problem.

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CosIng

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CosIng :

Cosmetic Ingredients, which is a database maintained by the European Commission that provides comprehensive information about cosmetic ingredients.

INCI names :

The International Nomenclature of Cosmetic Ingredients.

SCCS :

The Scientific Committee on Consumer Safety (SCCS)

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Annex No. (1): An illustrative list of cosmetic products

Annex No. (2): list of substances prohibited in cosmetic products

Ex : zinc pyrithione

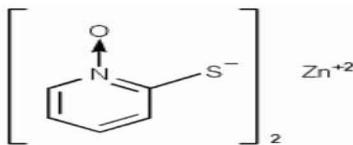
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CosIng - Cosmetics Ingredients

[Home \(/growth/tools-databases/cosing/\)](#) > ZINC PYRITHIONE

Ingredient: ZINC PYRITHIONE



INCI Name	ZINC PYRITHIONE
Description	<p>Zinc Pyrithione is the aromatic zinc compound</p> 
CAS #	13463-41-7
EC #	236-671-3
Identified INGREDIENTS or substances e.g.	<ul style="list-style-type: none"> Pyrithione zinc; (T-4)- bis[1-(hydroxy-.kappa.O)pyridine-2(1H)- thionato-.kappa.S]zinc (/growth/tools-databases/cosing/details/100284)
Cosmetics Regulation provisions	Annex II/1670
Functions	<ul style="list-style-type: none"> ANTI-SEBORRHEIC (/growth/tools-databases/cosing/reference/functions/list/ANTI-SEBORRHEIC) ANTI-SEBUM (/growth/tools-databases/cosing/reference/functions/list/ANTI-SEBUM) HAIR CONDITIONING (/growth/tools-databases/cosing/reference/functions/list/HAIR%20CONDITIONING) PRESERVATIVE (/growth/tools-databases/cosing/reference/functions/list/PRESERVATIVE)
SCCS opinions	<ul style="list-style-type: none"> Opinion concerning Zinc Pyrithione (http://ec.europa.eu/health/ph_risk/committees/sccp/documents/out225_en.pdf) Opinion on Zinc pyrithione P81 (http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_133.pdf) OPINION ON Zinc Pyrithione (ZPT) (CAS No 13463-41-7) -Submission III (https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_236.pdf) ADDENDUM to the scientific opinion on Zinc pyrithione (P81) ref. SCCS/1512/13 (https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_216.pdf)



Annex No. (3): list of substances which cosmetic products must not contain except subject to the restrictions laid down

Ex : salicylic acid

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Substance	Benzoic acid, 2-hydroxy-
CAS #	69-72-7
EC #	200-712-3
Name of Common Ingredients Glossary	SALICYLIC ACID
INN / ISO / AN	
Regulation	(EU) 2021/850
Other Directives / Regulations	
Annex / Ref #	III / 98
Product Type, body parts	(a) Rinse-off hair products (b) Other products except body lotion, eye shadow, mascara, eyeliner, lipstick, roll-on deodorant (c) Body lotion, eye shadow, mascara, eyeliner, lipstick, roll-on deodorant
Maximum concentration in ready for use preparation	(a) 3.0% (b) 2.0% (c) 0.5%
Other	(a) (b) (c) Not to be used in preparations for children under 3 years of age. Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation. Not to be used in oral products. For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product. These levels are inclusive of any use of salicylic acid.
Wording of conditions of use and warnings	(a) (b) (c) Not to be used for children under 3 years of age* * Solely for products which might be used for children under 3 years of age.



Annex No. (4): list of colorants allowed in cosmetic products
EX 42090, 42053 , 10316 , 11725

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Substance	2-[(4-Methoxy-2-nitrophenyl)azo]-3-oxo-N-(o-tolyl)butyramide
CAS #	6371-96-6
EC #	228-907-9
Colour index Number / Name of Common Ingredients Glossary	CI 11725
Colour	Orange
INN / ISO / AN	
Regulation	(EC) 2009/1223
Other Directives / Regulations	
Annex / Ref #	IV / 6
Product Type, body parts	
Maximum concentration in ready for use preparation	Rinse-off products
Other	
Wording of conditions of use and warnings	
SCCS opinions	
Chemical / IUPAC Name	2-[(4-Methoxy-2-nitrophenyl)azo]-3-oxo-N-(o-tolyl)butyramide



Annex No. (5): list of preservatives allowed in cosmetic products EX SODIUM BENZOATE ,

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Substance	Benzoic acid and its sodium salt
CAS #	65-85-0 / 532-32-1
EC #	200-618-2 / 208-534-8
Name of Common Ingredients Glossary	BENZOIC ACID; SODIUM BENZOATE
INN / ISO / AN	
Regulation	(EC) 2009/1223
Other Directives / Regulations	
Annex / Ref #	V / 1
Product Type, body parts	a) Rinse-off products, except oral care products b) Oral care products c) Leave-on products
Maximum concentration in ready for use preparation	a) 2.5% (acid) b) 1.7% (acid) c) 0.5% (acid)
Other	
Wording of conditions of use and warnings	



Annex No. (6): list of UV filters allowed in cosmetic products
EX: ETHYLHEXYL METHOXYCINNAMATE,
HOMOSALATE
OCTOCRYLENE, BENZOPHENONE 3

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Substance	2-Ethylhexyl 4-methoxycinnamate / Octinoxate
CAS #	5466-77-3
EC #	226-775-7
Name of Common Ingredients Glossary	ETHYLHEXYL METHOXYCINNAMATE
INN / ISO / AN	octinoxate
Regulation	(EC) 2009/1223
Other Directives / Regulations	
Annex / Ref #	VI / 12
Product Type, body parts	
Maximum concentration in ready for use preparation	10%
Other	
Wording of conditions of use and warnings	



7. Variations

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Do & Tell



- (The company can apply for the cosmetics variations after the modification is made to the product)

Variation type	Analysis
1-Size Addition/Deletion	Re-analysis is not required
2. Carton Box Addition/Deletion with a commitment to the registered data mentioned in the inner or/and outer pack	Re-analysis is not required
3. Pack Addition/Deletion	Re-analysis is not required
4. Shelf-Life Extension/Reduction (up to 5 years)	Re-analysis is not required

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Tell & Do



- **(The company shall apply for the Cosmetics Variations before changing the data of the approved product, and that type of variation shall not be applied except after getting Authority's Approval)**

Variation Type	Analysis
1. Changing composition form	Re-analysis is required
2. Changing the pharmaceutical form	Re-analysis is required
3. Updating the registration type from Imported to Under License and vice versa	Re-analysis is required
4. Adding a country of origin	Re-analysis is required
5. manufacturing transfer	Re-analysis is required
6. Adding manufacturing site	Re-analysis is required

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Variation Type	Analysis
7. Adding colors, fragrances and flavors	Re-analysis is required
8. Name Change	Re-analysis is not required
9. Adding a leaflet	Re-analysis is not required
10. Changing the purpose of use	Re-analysis is not required
11. Applicant's Name/Commercial Name change	Re-analysis is not required
12. Artwork change	Re-analysis is not required
13. Deleting a manufacturing site	Re-analysis is not required
14. Deleting a country of origin	Re-analysis is not required
15. Ownership transfer	Re-analysis is not required
16. Adding an artwork (private label) to the account of hotel chains or hypermarkets	Re-analysis is not required

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Thank You