

Claims Guide for Cosmetics Notification Year 2026

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Table of Contents

Content	Page
1. Introduction	3
2. Scope	3
3. Abbreviations	3
4. Definitions	3
5. List of unacceptable claims in cosmetic products	4
6. Skin massage products as cosmetics	5
7. Scar Improvement cosmetic products	6
8. Ingredients prohibited to be used in cosmetics	6
9. General technical requirements	7
10. General rules for using the electronic platform “EgyCosm”	7
11. Important websites	9
12. References	9
13. History table	10

1. Introduction

Objective: To guide applicant companies through the technical evaluation requirements for cosmetics, ensuring compliance and expediting the product approval process.

2. Scope

This guideline applies to the review of technical documentation for cosmetic product notifications, re-notifications, and variations.

3. Abbreviations

EDA: Egyptian Drug Authority

4. Definitions

4.1 Cosmetic Product: A Cosmetic product is defined as: "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."

4.2 Cosmetics Notification: The process of registering cosmetic products in the electronic database of EDA.

4.3 Cosmetics Variations: Any modification occurred to the registered cosmetic product and its attachments

4.4 Reference Countries: As per the decision of the Technical Committee of Cosmetics Registration on 29/06/2026, reference countries are Canada, USA, United Kingdom, Japan, Switzerland, Australia & European Union Countries (Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden).

4.5 Non-Reference Countries: They are the territories that are not listed in the reference countries.

4.6 Local Cosmetic Product: It is considered when the applicant has the authority to manufacture cosmetic products in its factory.

4.7 Toll-Manufacturing of Cosmetics: It is an outsourcing cosmetics production in which the applicant contracts with a cosmetics manufacturer to implement the process of manufacturing with or without storage.

4.8 Flagged Product: The product gets provisional approval, and a notification number is generated, but the applicant cannot apply for product variations and has two months to fulfill the requirements.

5. List of unacceptable claims in cosmetic products

The following claims are not allowed in cosmetic products:

1. Slimming,
2. Skin Tightening,
3. Body Contouring, Body Shaping, Redefine Body, Body Sculptor,
4. Prickly Heat,
5. Anti-callus,
6. Anti-inflammatory.
7. Anti- hyperhidrosis (Products for excessive sweating),
8. Anti Pimple*, Anti Acne,

9. Anti-Cellulite, Skin Sagging,
10. And “Prevent Stretch Marks”.

N.B. Compliance with European Union regulations regarding prohibited cosmetic claims is mandatory.

6. Skin massage products as cosmetics

Massage products shall have an approval for registration according to the following conditions:

1. The composition form shall not contain any substance (or its derivatives) that has a therapeutic effect, as follows: (This list is not exclusive)

- a) Willow bark extract
- b) MSM (Methyl Sulfonyl methane)
- c) Hyaluronic acid
- d) Capsicum
- e) Methyl salicylate
- f) Dimethyl sulfone
- g) Cetyl myristoleate
- h) Arnica extract
- i) Glucosamine
- j) Chondroitin
- k) Collagen
- l) Elastin
- m) Diosmin
- n) Hesperidin
- o) Cannabis
- p) Winter Green/ Glutheria extract

- q) Heparin
- r) Gelatin
- s) Piper Nigrum Seed Extract (Black Piper).

2. Claims that are not allowed

- a) "Fast or rapid action" phrases shall not be written.
- b) Any medical claim, suggestion or number of uses are not allowed to be written on the package.

3. It is not permitted to attach a leaflet with the product.

7. Scar Improvement cosmetic products

The products that have the purpose of **Emollient for Scar Improvement** as a primary purpose shall be registered as a cosmetic product in case of:

containing **>90% Silicone** or containing **≥ 10% Onion Extract**, provided that the company shall be committed to that the product's name does not contain "**Scar**" or "**Anti-scar**".

N.B. In case of violation of one of these conditions, the product cannot be notified as a cosmetic product.

8. Ingredients prohibited to be used in cosmetics

- The therapeutic substances such as: **Troxeutin, Escin, Permethrin, Ibuprofen, Naproxen** and similar substances, are prohibited to be registered in cosmetic products.
- **Silver / Nano Silver** substance is not permitted to be used in the products registered for the purpose of Skin Moisturizing / Soothing.
- **Methanol** is not permitted to be used in cosmetics.
- **Miconazole Nitrate** is not permitted to be used in cosmetics except for Hair- Care Products.
- **Tolnaftate** (Anti-fungal).
- **Diethyl Toluamide (DEET)** (insect repellent).

9. General technical requirements

Any amendment to the composition form on imported products during the notification process, shall be prohibited.

2. Cosmetics (except hair care products) shall not be diluted by the consumer and it shall be used as is.
3. The two substances **Beta-sitosterol and Sesame extract**, shall not be combined in one skin care product.
4. According to the decision of the Technical Committee of cosmetics Registration, the reference countries for the registration of cosmetic products are as follows:

European Union countries, the United Kingdom, the United States of America, Canada, Australia, Japan, and Switzerland.

10. General rules for using the electronic platform “EgyCosm”

- ❖ Any variation shall be carried out to the product before applying for renotification, as it is not permitted to make any change during the renotification. If any change is made during the re-notification, the request will be rejected and the product shall be submitted to the Variations department. A re-notification request shall be resubmitted after *paying new fees*.
- ❖ The **short name shall be a part of the long name**. The short name shall be written in the platform in the part designated for the short name.
- ❖ In case of products' ownership transfer to another company, none of the companies is allowed to perform **line extension** unless the ownership transfer of the **whole brand** is completed.
- ❖ In the case of **kit** notification, each product in the kit shall be notified separately, and then a request shall be submitted to notify the kit on the company's request.
- ❖ The type of product and the type of **registration** shall be checked. If the company commits an error during submission in the **Registration Type** (imported reference, imported non-reference, locally manufactured or toll manufactured), in the **product type** (ordinary product, dye, or kit), or in the **request type** (fast or normal), the request shall be rejected and resubmitted after *paying new fees*.
- ❖ It is not permitted to submit an appeal to amend the composition form for the **imported products**. The appeal shall be rejected in case of submission.

- ❖ It must be ensured that the factory license contains a **production line** before applying for notification. In case there is no production line, the product shall be rejected and the company shall be obligated to change the manufacturing site.
- ❖ In case of rejecting the request, the company has the right to submit two appeals for each notification request, after which the request shall be obsolete and a new request shall be submitted after *paying new fees*.
- ❖ It is not permitted to carry out more than one procedure on the product at the same time.
- ❖ In the case of the flagged products “**approve with comment**”)Flag), no procedure will be performed on it except after fulfilling the requirements (unflag).
- ❖ **The product’s re-notification** request shall be submitted **3 months** before the expiration of the notification validity so that the company can submit 2 appeals for the product when necessary, as it is not permitted to carry out any procedure on the product in case of expiring the validity of the re-notification.
- ❖ The specified **timeframe for any appeal** submitted by the company to the Authority during the notification is **30 days**. Upon expiring this period, the request shall be obsolete, the procedures of its completion shall be stopped and a new request shall be submitted for the product as a new product.
- ❖ In the event of arbitrating the circulation reference, a **free sale certificate** legalized by the **Egyptian embassy** shall be mandatory.
- ❖ In the event of arbitrating the manufacturing reference, the **manufacturing list** legalized by the **Chamber of Commerce** shall be mandated.
- ❖ In the case of registering **hair dye products or hair colorant kit**, the group name shall be added alongside the product name in long & short name places.
- ❖ In the case of **rejection of a variation request**, the period for fulfilling the comments shall be 15 days in the case of first rejection and an additional 15 days are granted for the second rejection. In the case of a third rejection, the company shall be prohibited to submit an appeal and a new request shall be submitted after *paying new fees*.
- ❖ In case of notifying a product with **multiple colors, fragrances, flavors, or all of them**, the service fee for each category shall be added to the notification fees that shown in the **Estimated Value** according to the list of the prescribed services fees.
- ❖ The Notification request shall be reviewed and the comments shall be sent to the company, without fees for once regarding the notification requirements in accordance with the regulatory guide for cosmetics notification (checklist). The company shall fulfill the requirements within 15 days then the request shall be technically reviewed, afterwards the final decision shall be issued, either approving and issuing the notification number or rejection. In case of rejection, the company has the right to submit an appeal twice for each request.
- ❖ The **services fees** must be paid and the original payment receipt must be submitted to the relevant administrator before submitting the notification request.

- ❖ The company shall submit the **original and legalized documents** to the pharmacists working in the administration to review the original documents before uploading them to the platform.

11. Important websites

1. Sun Screen Products

<http://data.europa.eu/eli/reco/2006/647/oj>

2. Guideline of Pharmaceutical Formulations Reference of Cosmetics "Frame Formulation"

<https://pdfcoffee.com/cosmetic-frame-formulations-pdf-free.html>

12. References

- European Guidelines (Cosmetics Ingredients Database-European Commission).
- Law no. 151 for the year 2019, chapter 1, article 1.7 & chapter 7, article 28
- EDA Chairman Decree No. (122) for the year 2022.
- Regulatory Guide for Cosmetics Notification, EDREX:GL.CAPP.009.
- Cosmetics Companies Portal User Manual, EDREX: NP. CAPP.075.

History Table

Version No.	Issue date	Summary of Changes
Version: 4	December 24th, 2023	_____
Version: 5	April 14th, 2025	• Updating the list of substances not allowed to be used in Massage Products by adding Heparin and Gelatin. • Revising Silicone Concentration to be more than 90% in Scar Improvement Products. • Adding Miconazole Nitrate to the list of Prohibited Ingredients in Cosmetics, except for Hair-Care Products. • Updating the General Requirements to include Reference Countries for The Registration of Cosmetic Products.
Version: 6	22 nd July 2026	• Updating the list of substances not allowed to be used in Massage Products by adding Piper Nigrum Seed Extract (Black Piper). • Adding Tolnaftate (Anti-fungal) and Diethyl Toluamide (DEET) (insect repellent) to the list of Prohibited Ingredients in Cosmetics.

* It is evaluated on a case-by-case basis according to the reference of the product.