

Requirements and Documents for Clearing Cosmetic Products from Customs Ports

Executive Directorate of cosmetics products
safety- Drug Sector

Required documents for clearance:

١. Commercial record of MOCI indicating the type of activity (perfumes & cosmetics).
٢. Authenticated conformity certificate from one of the approved companies (Intertek, SGS, TUV and Cotecna).
٣. Purchase invoice issued by the manufacturer.
٤. Country of origin certificate authenticated by the chamber of commerce at the country of origin
٥. A copy from agency registration document issued by MOCI in KSA or an original letter from the Manufacturer authorizing the importer to import and distribute their products in KSA.
٦. A bill of lading's copy.

Samples that used for personal purposes or ordered /purchased by internet and/or post :

For products that is purchased for personal purposes, please adhere to the following instructions:

- ١- The amount of samples should not exceed ١٠ packets or ٨ kilograms (which is the least).
- ٢- Complete the relevant application and sign the declaration of taking all the responsibilities of any side effects that might result of using the purchased products.
- ٣- Send the application to the Executive Directorate of Cosmetics Safety through: cosmetic@sfda.gov.sa or by fax: ٠١١ ٢٠٥ ٧٦٦١

Samples for analysis in laboratories in KSA:

Samples imported for the purpose of analysis will be cleared by a letter from a private laboratory indicating the amount of the sample and the purpose of analysis, the amount of the sample should not exceed ٣ packages of one sample.

Samples of advertising and marketing:

All the requirements of the commercial quantities are applied if the quantity excess the limit of the personal use . If there is any medical claim or ingredients that are used medically or they present in a pharmaceutical form that might be misused, they will be referred directly to the classification committee to decide whether they register them or not.

Clearance procedures:

First: If the product is attached with a certificate of conformity:

It shall be directly cleared after inspecting the following:

- Marking on the product's label which shall included:
 ١. A Product name and brand or trade mark.
 ٢. The name and address of the agent or importer in KSA.
 ٣. List of ingredients comprising more than ١٪ from the overall weight of the product. Also, it should be listed in descending order according to weight and shall follow the International Nomenclature System (INCI).
 ٤. The function of the product unless it indicated from the way of its presentation.
 ٥. Storage conditions
 ٦. Batch number, manufacturing date and validity period.
 ٧. Cautions or precautions
 ٨. Usage instructions
- No medical claims unless stated in the definition of cosmetic products as follows:

Any substance or preparation intended to be placed in contact with the various external parts of 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 includes the following products:

- Creams, emulsions, lotions, gels and oils for the skin (hands, face, feet, etc.).
- Face masks (with the exception of peeling products).
- Tinted bases (liquids, pastes, powders).
- Make-up powders, after-bath powders, hygienic powders, etc.
- Toilet soaps, deodorant soaps, etc.
- Perfumes, toilet waters and eau de cologne.
- Bath and shower preparations (salts, foams, oils, gels, etc.).
- Depilatories.

- Deodorants and anti-pereprints.
- Hair care products:
 - * hair tints and bleaches,
 - * products for waving, straightening and fixing,
 - * setting products,
 - * cleansing products (lotions, powders, shampoos),
 - * conditioning products (lotions, creams, oils),
 - * hairdressing products (lotions, lacquers, brilliantines).
- Shaving products (creams, foams, lotions, etc.).
- Products for making up and removing make-up from the face and eyes.
- Products intended for application to lips.
- Products for care of teeth and mouth.
- Products for nail care and make-up.
- Products for external intimate hygiene.
- Sunbathing products.
- Products for tanning without sun.
- Skin-whitening products.
- Anti-wrinkle products.
- Eye decorative cosmetic products (Eye shadow, Mascara, brows, lids, pencil, lashes, cream and athmad (Al-kohol)).

The label on the product shall not contain any medical or therapeutic claims; otherwise it will not be released until it is registered in SFDA as a medicine

Examples of non-allowed medical claims:

- Baldness treatment
- Pressure and diabetes treatment
- Sexual weakness treatment

Examples of claims compatible with cosmetic products definition:

- Preserving hair smoothness
- Nails strengthen
- Skin smoothing

Second: when a certificate of conformity is not available:

Clearance responsible personnel shall withdraw samples from the consignment and send it for the laboratory analysis, accompanied with a cheque issued by the importer (agent) to cover the charges, to ensure that the product does not contain any prohibited or restricted substances according to the Saudi standards and/or GSO standards for cosmetic products and to verify manufacturer's marking and the label.

Third: When a notification or warning is received regarding a product:
It shall be tested even if it is accompanied by a certificate of conformity.

Fourth: If the clearance responsible personnel noticed any problem during inspection like changes in the external appearance or material deterioration:

It shall not be cleared till it is tested.

Fifth: when one of the following is noticed on the imported products:

- ١- Existence of a medical claim such as (e.g. treating the acne and psoriasis).
- ٢- If the product exists in a pharmaceutical form(e.g. capsule, ampoule, tablet, drops).
- ٣- The presence of a substance that has any proved therapeutic or pharmaceutical claim.(e.g. Vitamin A, Salicylic acid, hydroquinone).

If any of the previous notices are observed, samples will be taken from the shipment. After that, a letter of classification request will be sent to the vice president of the drug sector with a list of samples, a copy of the invoice, bill of lading, import declaration, certificate of origin and certificate of confirmatory to decide whether the product is allowed or should be registered or refused.

Required samples for analysis: ٣ samples of each class

Samples for classification: ٢ samples

Sixth: When there is a problem in the product that needs analysis:

The agent can store the shipment after signing a pledge not to dispose the pending products until the result of analysis is issued and received an informing letter from the authority.

The information that shall be available on the cosmetic product label:

S/N	Required Information	On product's package	On outer package
١	Product name and trade mark (in Arabic or both Arabic and English)	√	√
٢	Name and address of manufacturer	√	√
٣	Name and address of the Importer (agent) in KSA	√	√
٤	List of ingredients	Shall be clear to consumer	
٥	Storage conditions	√	√
٦	Batch Number	√	√
٧	Expiry date (in Arabic or both Arabic and English)	√	√
٨	Usage instructions	√	√
٩	Function of the product unless it is indicated from the form of its presentation.	√	√
١٠	Use warnings (in Arabic or both Arabic and English)	√	√

Frequently asked questions:

Q: Is it required to register cosmetic products at SFDA before importation?

A: At the moment it is not required to register cosmetic products before importation. SFDA is building up an electronic system to register the cosmetic products , eventually it will be a condition for importation, and will be announced once completed on our website <http://www.sfda.gov.sa> .

Q: Are there any list for the companies that are approved to issue conformity certificates?

A: Yes, Currently the SFDA accredited on several companies to issue a certificate of conformity :

- ١-(Intertek International Limited)
- ٢-(SGS Socirte Generale de Surveillance)
- ٣-(TUV Rheinland)
- ٤- Cotecna

In case the SFDA depend on others companies we will announced it.

Q: What are the requirements of the conformity certificates?

A: The certificate of conformity shall be issued by an accredited certification company at the country of origin and shall be attested. In addition, the certificate shall state that the product complies with Saudi standards issued by the Saudi Standards, Metrology and Quality Organization (SASO) and/or GSO Standards.

Q: Is it possible to import products accompanied by certificate for standards other than one which issued by SASO and/or GSO Standard?

A: It is not permitted to import cosmetic products unless the certificate of conformity states that the product complies with SASO standards and/or GSO Standard.

Q: I wish to ensure compliance of the product's label to what is approved by SFDA?

A: Compliance of the product label can be ensured by implementing the requirements of SASO ١٩٥٣ and/or (GSO ١٩٤٣/٢٠٠٩) (Cosmetic Products – The Cosmetic Product (Safety) Regulations). At the moment, this requirement and other cosmetic products related standards can be obtained from SASO and/or GSO website, and in the future it will be possible to have them from the SFDA website.

Q: I would like to import products but I am not entirely certain whether it is considered as cosmetic product or medicine?

A: It can be ensured that the product to be imported are cosmetic products by implementing the definition of cosmetic products of SASO and/or (GSO ١٩٤٣/٢٠٠٩) (Cosmetic Products – The Cosmetic Product (Safety) Regulations), and it is possible to apply for the SFDA to determine whether it requires registration as medicine or not.

Q:I have a letter classification of the Ministry of Health the fact that the product is not subject to registration, can I import accordingly?

A. clearance can be made according the letter of classification issued by the Ministry of Health **only once** , The importer must Apply for classification in SFDA if he want to make sure that the product is subjected to registration or not.