



Kingdom of Saudi Arabia
Saudi Food & Drug Authority



Conditions of Cosmetic

**Products Clearance and Raw Materials
used in their Manufacturing**

Version No. 3, 5

Vision and Mission of the Saudi Food and Drug Authority



Our vision...

Is based on scientific principles to enhance and protect, aiming to become a globally leading authority in public health.



Our mission...

To protect the community through effective legislation and regulatory system to ensure the safety of food, drugs, medical devices, cosmetics, pesticides, and feed products.

Document Control

Version	Date	Author	Comments
1	17 June, 2015	Executive Department of Cosmetic Products Safety	Final
2	01 February, 2017	Executive Department of Cosmetic Products Safety	Update
2,1	05 November, 2017	Executive Department of Cosmetic Products Safety	Update
3	29 April, 2019	Clearance Department and Ports Support (Operation Sector)	Update
3,1	12 September, 2019	Clearance Department and Ports Support (Operation Sector)	Update
3,2	27 November, 2019	Clearance Department and Ports Support (Operation Sector)	Update
3,3	30 August, 2020	Clearance Department and Ports Support (Operation Sector)	Update
3,4	22 June, 2021	Clearance Department and Ports Support (Operation Sector)	Update
3,5	08 March, 2022	Clearance Department and Ports Support (Operation Sector)	Update (the following page states the items)

What is the update in this version No. (3,5)?

The following page explains the updates:

Address	Update type
Changing the title	From "Requirements and Documents required for Clearing Cosmetic Products through Customs Ports" to " Conditions of Cosmetic Products Clearance and Raw Materials used in their Manufacturing".
General Conditions	<p>Add: 6,3 Clearance application should be submitted electronically to the sector's office at port of arrival via FASH Service at GHAD. In addition the application should be submitted via Fasah platform (Tabadul).</p>
	<p>Comply with the Authority Circular No. 31110 dated 23/06/1439 A.H concerning Keeping Original Copies of the Documents Required for Clearance.</p> <p>Add: It is necessary to keep the clearance original documents for a period no less than 5 years.</p>
	Comply with the Authority Circular concerning fast track of products registered at the Authority.
Requirements and Documents required for Clearance of Dispatches and Commercial Quantities of Cosmetic Products or Marketing Samples	<p>The above requests shall be attached with the application submitted via Fasah platform (Tabadul) to be referred to the Authority for completion of procedures required for clearance.</p> <p>Add: The above documents shall be attached electronically with the application submitted via electronic platforms for completion of procedures required for clearance.</p>

Address	Update type
	<p>Delete: Any Conformity Certificate issued by any company not approved by the Authority nor published in the Authority website shall not be approved. Moreover, no conformity certificate shall be approved if the cargo manifests are not in conformity with the attached certificate. The importer shall not use this certificate for more than one dispatch and the importer should issue a certificate for each dispatch separately unless they are holding the same batch number.</p> <p>Add: Any Conformity Certificate not issued via Fasah electronic platform for clearing cosmetic products shall not be approved.</p>
<p>Requirements and Documents required for Clearance of Marketing Samples Dispatches</p>	<p>Add: The requirements and documents required for them.</p>



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Definitions:

Cosmetic Product:

any product that contain one or more substance prepared to be placed at the external parts of human body (epidermis, hair, nails, lips or external genital organs or with teeth and the mucous membranes of the oral cavity; to clean or perfume them or protect them or keep them in good condition or exchange their appearance and improve it or change body odor or refine it.

Notification:

registering a cosmetic product in cosmetic products list after being approved by the Authority.

Manufacture/Laboratory:

the facility where the cosmetic product is manufactured.

Warehouse:

the licensed place where the cosmetic product is stored and distributed.

Conformity Assessment Bodies:

it is the body that check the products' and/ or establishments and /or manufactures conformity to the Authority specifications and requirements including inspection bodies, bodies that grant certificates, laboratories and any other conformity assessment bodies that the Authority may add due to its activity in future.

Conformity Certificate:

a third party authentication of products or operations or systems or persons.



Authorization:

Based on Saudi Food and Drug Authority Regulation issued under No. 4693/ج dated 26/01/1428 and what is stated in point (7) of the regulatory missions assigned to the Authority according to the fifth clause and subject to Cosmetic Product Regulation promulgated in the royal Decree No. 49/م dated 18/06/1436 A.H and Executive Regulation thereof issued by the SFDA Board, the Authority drafted the specifications and requirements concerning clearing all what is stated under the scope of this instrument.



References:

- The Executive Regulation for eCosma .
- The Executive Regulation for Importing Chemical Substances.



Scope:

All cosmetic products, bulks that are imported for the purpose of repackaging or filling, feedstock chemicals for local cosmetic products manufactures and empty containers for filling or packaging cosmetic products.



Object :

Explain the specifications and requirements of cosmetic products clearance through customs ports.



General Conditions:

- 6-1 Cosmetic products that are prepared for commercial usage should be notified at the Authority via eCosma.
- 6-2 It is necessary to comply with the Regulation on Requirements of Cosmetics and Personal Care Safety" No. SFDA.CO/GSO 1943 according to the latest update thereto and circulars issued by the Authority.
- 6-3 Clearance application should be submitted electronically to the sector's office at port of arrival via FASH Service at GHAD. In addition the application should be submitted via Fasah platform (Tabadul).
- 6-4 You should keep the clearance original documents for a period no less than 5 years.
- 6-5 Products that are cleared from ports at fast clearance without inspection (based on the risks), the supplier shall be liable for inspecting the imported products and ensure that they meet the standard regulations and specifications according to the regulations added at the Authority.

6-6 Comply with all what is stated in Code of Transport and Storage of Products Subject to the Supervision of Pharmaceutical Sector through Customs Ports published at the Authority website.

6-7 List of Inspection, Conformity Offices and Private Laboratories appointed by the Authority.

6-8 Conditions and requirements for clearance or exporting for individuals for the purpose of personal usage.

Requirements and Documents required for Clearance of shipments and Commercial Quantities of Cosmetic Products:



Requirements:

Notification of the cosmetic product in eCosma.

Documents to be submitted for clearance:

1- Copy of Payment bill

Payment bill should be endorsed from chamber of commerce at country of consignment. Moreover, it should include the following details:

- The name of manufacturer company and its nationality.
- Bill number and date.
- Product name.
- Batch or dispatch number or production date

2- Certificate of Conformity:

Certificate of Conformity should be issued by a company that is approved at the Authority. It is defined as a certificate that proves that the imported product at the dispatch and under the bill number and batch number attached in the certificate are in conformity with Regulation on Requirements of Cosmetics and Personal Care Safety No. SFDA.CO/GSO 1943 according to the latest update thereto and circulars issued by the Authority before importing it to the Kingdom.

For knowing conformity companies approved at the Authority that are continually updated at the Authority website, kindly visit the following page:

List of Inspection, Conformity Offices and Private Laboratories appointed by the Authority.

Any Conformity Certificate not issued via Fasah electronic platform for clearing cosmetic products shall not be approved.

If the product is notified and conformity certificate was not attached with the consignment, samples from the imported dispatch shall be withdrawn and sent to the private laboratories assigned by the Authority under the Regulation on Appointment of Conformity Assessment Bodies and Private Laboratories for the purpose of analyzing and inspecting its conformity to the Authority specifications provided that the importer shall bear the costs of sample analysis and testing. The consignment shall be cleared under pledge not to dispose of the dispatch and waiting for the results of examination.

3- Copy of bill of lading

4- The above documents shall be attached electronically with the application submitted via electronic platforms for completion of procedures required for clearance.



Requirements and Documents required for Clearance of Marketing Samples Dispatches:

- Notify the cosmetic product in eCosma.
- The quantity allowed to be cleared shall be 5 containers of each item.

Documents to be submitted for clearance:

1- A letter from the importer explains that samples are for the purpose of marketing inside the establishment not for sale.

2- Copy of payment bill

Payment bill should be endorsed from chamber of commerce at country of consignment. Moreover, it should include the following details:

- The name of manufacturer company and its nationality.
- Bill number and date.
- Product name.
- Batch or dispatch number or production date

3- Copy of bill of lading

4- The above documents shall be attached electronically with the application submitted via electronic platforms for completion of procedures required for clearance.



Samples for the Purpose of Testing in the Private Laborites inside the Kingdom:

Samples for the purpose of testing in the private laboratories authorized by the Authority shall be cleared subject to a letter from the private laboratory stating therein the sample quantity. The test object is ensure that quantity of the samples of one type shall not exceed the number allowed for personal usage.



Conditions and Requirements for Clearance of Bulks that are imported for the Purpose of Repackaging or Filling

Requirements:

- 1- Notify the cosmetic product in eCosma.
- 2- It is not permitted to mix or add any other substances to the final product.
- 3- The manufacture or laboratory should be licensed by the Authority.

Documents to be submitted for Clearance:

Requirements for Clearance of Dispatches and Commercial Quantities of Cosmetic Products stated in point No. 6 of this guide.



Conditions and Requirements for Feedstock Chemicals Clearance for Local Cosmetic Product Manufactures.

Important notes:

- Operation Sector is liable for importing and clearing chemical substances used for healthy purposes or used in composition of cosmetics or products that under the Authority supervision only.
- Clearance of chemical substances shall be for pharmaceutical, cosmetic manufactures, pharmacies and laboratories authorized by Saudi Food and Drug Authority and health authorities.
- Importing and clearing the chemical precursor referred thereto in the executive regulation of program of importing chemical substances of the second and third list shall be made through Narcotic Drugs Administration at the headquarter of Drug Sector in Riyadh.
- The containers of chemical substances should contain the artwork that includes the information of the transported substance and how to store and transport it.
- You can obtain the below forms (No. 1, 2, 8 and 10) of the executive regulation for law of importing chemicals published at the Authority website (laws and regulations page).

First: Clearance of dangerous chemicals that are used in explosion composition (First list):

Procedures for obtaining clearance permit:

1- The importer who obtain a permission for importing chemical substances should submit to the Ministry of Interior (General Secretary of Industrial Security High Commission - Central Licensing Unit) a letter includes an application for obtaining clearance permit for each imported consignment within a period no less than ten working days before the actual date of the consignment arrival.

2-The Ministry of Interior (General Secretary of Industrial Security High Commission- Central Licensing Unit)) shall complete the procedures of the application for obtaining clearance permit, issue, approve and send original copy of clearance permit to the customs.

• Document required to submitted to Industrial Security to obtain clearance permit:

A latter includes an application for obtaining clearance permit for chemical substances addressed to the Ministry of Interior (General Secretary of Industrial Security High Commission- Central Licensing Unit) accompanied with the following:

1- Form of application for clearance permit of chemical substances form No. (10) after filling all fields.

2- Copy of a valid import permit issued by the Industrial Security.

3- Clear copy of payment bill including the bill number, date, name and address of the manufacturer and importer company, scientific and commercial name of the chemical substances and its quantities in clear and legible writing into English and Arabic.

4- Clear copy of Origin Certificate signed, stamped and approved by the concerned authorities in the country of origin.

Note: if the Authority approved the application, it shall give orders to issue import permit by addressing the Industrial Security at the Ministry of Interiors by recommendations and then import and clearance permit shall be issued by them.

Second: Clearance of unregistered or banned chemical substances (the ninth list)

Procedures to be submitted required for obtaining clearance permit:

The importer who obtain a permit for importing chemical substances should provide Operation Sector at arrival port with a letter includes an application for obtaining a permit for clearing each imported consignment within a period no less than ten working days before the actual date of the

- **Documents to be submitted for obtaining Clearance Permit:**

A letter addressed to the Authority office at arrival port for clearance application accompanied with the following:

- 1- Form of application for Chemicals Clearance Permit form No. (10) after filling all fields.
- 2- Copy of valid import permit.
- 3- Clear copy of payment bill including the bill number, date, name and address of the manufacturer and importer company, scientific and commercial name of the chemical substances and its quantities in clear and legible writing into English and Arabic.
- 4- Clear copy of certificate of origin signed, stamped and approved by the concerned authorities in country of origin.
- 5- Clear copy of material safety data sheet (MSDS) into English stamped with the importer's stamp translated into Arabic by a certified translation office.
- 6- The above requests shall be attached with the application submitted via Fasah platform (Tabadul) to be referred to the Authority after completion of clearance procedures.

- **It is necessary to review the general conditions and notes stated herein and comply with what is stated therein.**



Conditions and Requirements for Clearance of Empty Containers for Filling or Packaging Cosmetic Products

Requirements:

- It is not permitted to clear containers that bear brands or trademarks that are not related to the importer without the manufacture(the beneficiary)approval.
- Manufacture or laboratory or warehouse authorized from the Authority.

Documents to be submitted for Clearance application:

1- A letter from the importer addressed to the sector's office at arrival port requesting approval to clear the empty containers including the following:

The purpose of importing the empty containers and undertaking to use it for the intended purpose.

Names of items, quantities and name of manufacturer company.

2- Copy of payment bill endorsed from chamber of commerce at the country of origin or the country where the bills are issued.

3- Copy of bill of lading .

4- Copy of the manufacture or laboratory or warehouse license.

5- The above requests shall be attached with the application submitted via Fasah platform (Tabadul) to be referred to the Authority after completion of clearance procedures.



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