

# شــعبــة الــتــرجــمــة الرســميــة Official Translation Department

# **Cosmetics Law**

Royal Decree No. M/49 April 7, 2015

**Translation of Saudi Laws** 



#### NOTE:

The translation of Saudi laws takes the following into consideration:

- Words used in the singular form include the plural and vice versa.
- Words used in the masculine form include the feminine.
- Words used in the present tense include the present as well as the future.
- The word "person" or "persons" and their related pronouns (he, his, him, they, their, them) refer to a natural and legal person.



## **Cosmetics Law**

## Article 1

In this Law, the following terms and phrases shall have the meanings assigned thereto, unless the context requires otherwise:

- 1. Law: The Cosmetics Law.
- 2. **Regulations**: The implementing regulations of this Law.
- 3. Authority: The Saudi Food and Drug Authority.
- 4. Board: The Authority's Board of Directors.
- 5. **President**: The Chief Executive Officer of the Authority.
- 6. Cosmetic Product: Any product containing one or more substances that is intended for external use, including skin, hair, nails, lips, the external parts of the genitals, teeth, or membranes lining the oral cavity, for cleansing, perfuming, caring, beautifying, and protection purposes, or for changing and improving body odor.
- 7. **Listing**: Registering the cosmetic product in the relevant cosmetics register after being approved by the Authority.
- 8. Listing Person: The natural or legal person under whose name the cosmetic product is registered at the Authority.
- 9. Factory: The local facility where the cosmetic product is manufactured.
- 10. **Good Manufacturing Practices**: A quality assurance system which ensures that the cosmetic product is produced in accordance with high and appropriate quality standards.
- 11. **Warehouse**: A location licensed by the Authority to store and distribute a cosmetic product for commercial purposes.
- 12. **Laboratory**: A laboratory assigned by the Authority to analyze and examine cosmetic products.
- 13. **Circulation**: The stages through which a cosmetic product passes until delivery to the consumer, including import, export, manufacturing, preparation, processing, packaging, wrapping, preparing, storing, transportation, possession, marketing, distribution, display, merchandising, and sampling.
- 14. **Withdrawal**: The withdrawal of a cosmetic product from the market by the Authority following certain procedures or measures.
- 15. **Recall**: The procedures or measures taken by the listing person, at his own initiative or upon the request of the Authority, to retrieve a cosmetic product which is not safe for consumer use or is in violation of this Law, and to prohibit the circulation thereof.
- 16. **Counterfeit Product**: A cosmetic product the content, identity, or source of which is deliberately changed, whether it contains the same components,



improper components, or no components, or contains contaminated substances.

- 17. **Spoiled Product**: A cosmetic product whose physical and chemical properties or bacterial content have changed.
- 18. Advertisement: Any statement, whether written, audio, visual, or otherwise, which aims to directly or indirectly promote, sell, or market cosmetic products.

## Article 2

This Law shall apply to cosmetic products, including their factories and warehouses, as well as the circulation of and trading in such products.

#### Article 3

The Authority shall issue the technical regulations and standard specifications for cosmetic products and their factories, as well as the requirements for their workers.

#### Article 4

The Authority shall prescribe substances the use of which in cosmetic products is prohibited or restricted, and post the same on its website.

#### Article 5

The Authority shall verify the compliance of cosmetic products with the technical regulations, standard specifications, and conditions, and may for this purpose seek the assistance of specialized companies.

#### Article 6

A cosmetic product may not be imported or circulated in the Kingdom unless it is listed with the Authority and a listing certificate is obtained therefrom in accordance with the rules and conditions specified in the regulations.

#### Article 7

The application for listing a cosmetic product shall be submitted by the factory or company, or their representatives, in accordance with the procedures and conditions specified in the regulations.

#### Article 8

The Authority shall decide on the listing application within 15 days following completion of the requirements. If the application is accepted, a listing certificate shall be issued; if, however, the application is rejected or no decision is rendered thereon, the Authority shall provide justification therefor.



The listing person shall ensure that the cosmetic product:

- 1. is safe; and
- 2. does not cause any harm to the consumer's health if, under normal circumstances, the product is used in accordance with the usage and disposal instructions indicated on the identification label.

# Article 10

The listing person shall:

- 1. notify the Authority if the cosmetic product causes harm to its users, contains a manufacturing defect, or is recalled in any country;
- 2. keep the product information file and present it to the Authority upon request;
- 3. notify the Authority of any modification to the product;
- 4. document the wholesale of the product; and
- 5. notify the Authority of any misuse of the product.

## Article 11

Cosmetic products shall be labeled in accordance with the regulations.

## Article 12

The Authority shall publish on its website the cosmetic products listed in the relevant cosmetics register.

## Article 13

A technical license for the factory shall be obtained from the Authority in accordance with the requirements and conditions specified in the regulations.

#### Article 14

The technical license for the factory shall be obtained in accordance with the following procedures:

- An application shall be submitted to the Authority in accordance with the requirements and conditions specified in the regulations. The Authority shall decide on the application within 30 days following completion of the requirements. If the application is accepted, the Authority shall issue a document of initial approval; if, however, the application is rejected, the Authority shall provide justification therefor.
- 2. The Authority shall issue a license to the factory after the applicant obtains the necessary approvals from the relevant agencies, and after the Authority verifies the factory's compliance with the good manufacturing practices approved thereby.



The factory shall have a full-time Saudi technical manager as specified in the regulations.

## Article 16

The factory shall notify the Authority of any change to the factory, its products, or the information it presented. The factory may not be operated for purposes other than those for which it is licensed.

## Article 17

The factory may not market the cosmetic product unless it is listed.

## Article 18

The factory shall comply with the good manufacturing practices and the Authority may, when necessary, verify the same in accordance with the procedures specified in the regulations.

## Article 19

A warehouse license shall be obtained from the Authority in accordance with the requirements and conditions specified in the regulations.

#### Article 20

The factory and warehouse license shall be for a term of five renewable years.

#### Article 21

Advertising or promoting cosmetic products may not be made before being listed and shall be subject to the rules and conditions specified in the regulations.

#### Article 22

Without prejudice to the jurisdiction of the Ministry of Health provided for in the Private Healthcare Institutions Law and the Pharmaceutical Institutions and Products Law, the Authority shall supervise and inspect the factories, warehouses, sale locations, consignments, and shipments of cosmetic products.

#### Article 23

If the Authority considers the cosmetic product to be detrimental to public health, it shall warn against using its use through the methods it deems appropriate.



If the Authority establishes that the cosmetic product is unsafe or detrimental to health, or if it is not listed, it shall take one or more of the following measures:

- 1. Delisting the product.
- 2. Prohibiting its circulation.
- 3. Withdrawing or recalling it.
- 4. Suspending its circulation for a specific period.

## Article 25

If the Authority suspects that the cosmetic product is in violation of this Law or its regulations, it may suspend its circulation for a specific period.

## Article 26

The listing person shall comply with the Authority's decision to withdraw or recall a cosmetic product within the period determined thereby. If he fails to do so, the Authority shall withdraw and destroy the product, as the case may be, at his expense, in accordance with procedures determined by the regulations.

## Article 27

A cosmetic product which has been delisted, prohibited, withdrawn, recalled, or suspended by the Authority may not be circulated.

#### Article 28

The Authority's inspectors may collect samples of cosmetic products to be examined and analyzed in accordance with rules and conditions specified in the regulations.

#### Article 29

Recording of violations of this Law and its regulations shall be made by employees nominated by the President; such employees shall have the powers of preliminary criminal investigation officers.

#### Article 30

Officials and employees at the locations to be inspected may not obstruct the work of the Authority inspectors and shall provide them with the required information, documents, and samples.

#### Article 31

Any person who commits or attempts to commit one or more of the following acts shall be considered in violation of this Law:

1. Counterfeiting cosmetic products.



- 2. Circulating a cosmetic product which is counterfeit, spoiled, expired, or is in violation of its listed details.
- 3. Using false information in the advertisement of the cosmetic product or on the product itself for promotion purposes.
- 4. Bringing into the Kingdom packages or containers for the purpose of counterfeiting a cosmetic product.
- 5. Manufacturing, printing, possessing, displaying, or selling packages or containers for the purpose of counterfeiting a cosmetic product.
- 6. Presenting incorrect information to the Authority related to the cosmetic product.
- 7. Importing, exporting, re-exporting, manufacturing, marketing, selling, displaying, or storing a cosmetic product for his own benefit or the benefit of another person in violation of this Law or its Regulations.
- 8. Obstructing the work of the Authority inspectors by preventing them from entering the factory, warehouse, or sale location, or from collecting samples of the cosmetic product.

If any product in violation of this Law or its Regulations is seized, the following measures shall be taken:

- 1. Confiscating the product along with its related documents, when necessary.
- 2. Collecting samples from the product for analysis, when necessary.
- 3. Destroying the product if spoiled.
- 4. Destroying the product if counterfeit.
- 5. Destroying the product if not listed.

#### Article 33

The destruction process shall be conducted by one or more committees formed for this purpose; the formation and work procedures of such committees shall be determined by the Regulations. The violator shall bear the expenses of the destruction process.

#### Article 34

Without prejudice to any harsher penalty provided for in any other Law, a person who violates this Law or its Regulations shall be subject to one or more of the following penalties:

- 1. A fine not exceeding five million riyals.
- 2. Closing the factory or warehouse until the violation is rectified.
- 3. Canceling the license of the factory or warehouse.
- 4. Imprisonment for a term not exceeding five years.



If the violation is repeated, the penalty may be doubled.

## Article 35

- 1. The Board shall issue a schedule which includes classification of the violations along with their corresponding penalties.
- 2. The Authority shall consider administrative violations and impose the penalties provided for in Article 34 of this Law, except for the imprisonment penalty, in accordance with rules and procedures determined by the Board.
- 3. Violations which constitute offenses pursuant to Article 31 of this Law shall be referred by the Authority to the Public Prosecution for investigation and prosecution, and for taking legal action to refer such violations to the competent court.
- 4. The Authority may, during the investigation or trial period, close the factory or warehouse for a specified period or until the violation is rectified.
- 5. The Authority may publish the penalty decision at the expense of the violator.

#### Article 36

- 1. The Board shall form one committee, or more, to consider the appeals filed against penalty decisions issued by the Authority. The committee shall be composed of three members or more, and shall comprise at least one legal consultant.
- 2. The penalty decision issued by the Authority may be appealed before the committee within 30 days from the notification date of the penalty decision, provided the committee considers such appeals within a period not exceeding 60 days.
- 3. If the committee does not issue a decision within the period specified in paragraph 2 or if the violator does not accept the committee's decision, the violator may file an appeal with the Board of Grievances within 60 days from the date the committee's decision is issued or from the date the period specified for considering the appeals before the committee expires.
- 4. The Board shall determine the committee's work procedures and the remuneration of its members.

#### Article 37

The Implementing Regulations of this Law shall be issued by the Board and shall come into effect on the date the Law comes into effect.

#### Article 38

This Law shall come into effect 180 days following the date of its publication in the Official Gazette.