



Hand Cleansing Gel / Alcohol Based Hand Sanitizers in Saudi Arabia

White Paper

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Hand sanitizers are a common product used for hygiene purposes like cleaning hands when water is not easily accessible. Since 2020, these products have been on the front line, helping us fight the COVID-19 pandemic. Hand sanitizers are now part of our daily lives. No one today could imagine leaving the house without a bottle of gel!

In this paper we will look at how these products are regulated, what are the rules to follow, and how to ensure safety and efficacy of these products. Hand sanitizers are indeed not only used to clean hand, but to remove bacteria and protect users. In Saudi Arabia, as in many other countries, these products are not placed on the market as a cosmetic if their main purpose is to kill bacteria and not simply clean hands.

We will determine in which case the products will be classified as cosmetics, or health products.

Placing such products on the market poses several questions, and the first would be to determine the relevant classification and the requirements, that may differ from one country or region to another.

The question of efficacy, in these times of pandemic is also a very important concern as the main purpose of these products is to protect the population.

1. WHAT IS HAND SANITIZER?



A hand sanitizer is a preparation used to clean hands and kill bacteria. It can be in the form of gel or hydroalcoholic solutions that are disinfectant products intended to eliminate bacteria or viruses from healthy skin. It is an alternative to hand washing (with water and soap) that is widely recommended in pandemic times.

It can be in the form of liquid or gel, foam or other (like sprays) – the finished form of the products does not affect its efficacy, provided that the composition follow the recommendations on the minimum alcohol or active matter content.

2. DEFINITIONS AS PER SFDA

The Saudi Food and Drug Authority (SFDA) is an independent body reporting directly to the President of the Council of Ministers. The SFDA ensures the safety of food and drugs for human and animal consumption, and the safety of biological and chemical substances, and electronic products, being imported into the Kingdom of Saudi Arabia.

In Saudi Arabia, hand cleansing gels or hand sanitizers fall under the SFDA Cosmetics programme and can be classified under these two categories:

Official definition GSO 1943/2021

2.1 Cosmetic and Personal Care Products:

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.

2.2 Health Product:

Finished labelled products in pharmaceutical dosage form. Usually made from low risk ingredients intended to restore, correct, or modify physiological functions by exerting pharmacological, immunological or metabolic assets.

There is no definition of "biocides" in Saudi Arabia, as this category does not exist yet.

3. SFDA REGISTRATION PROCESS

REGISTERING WITH SFDA

IMPORTANT

Files provided must be well organized with the documents clearly labelled using the product name or reference code.

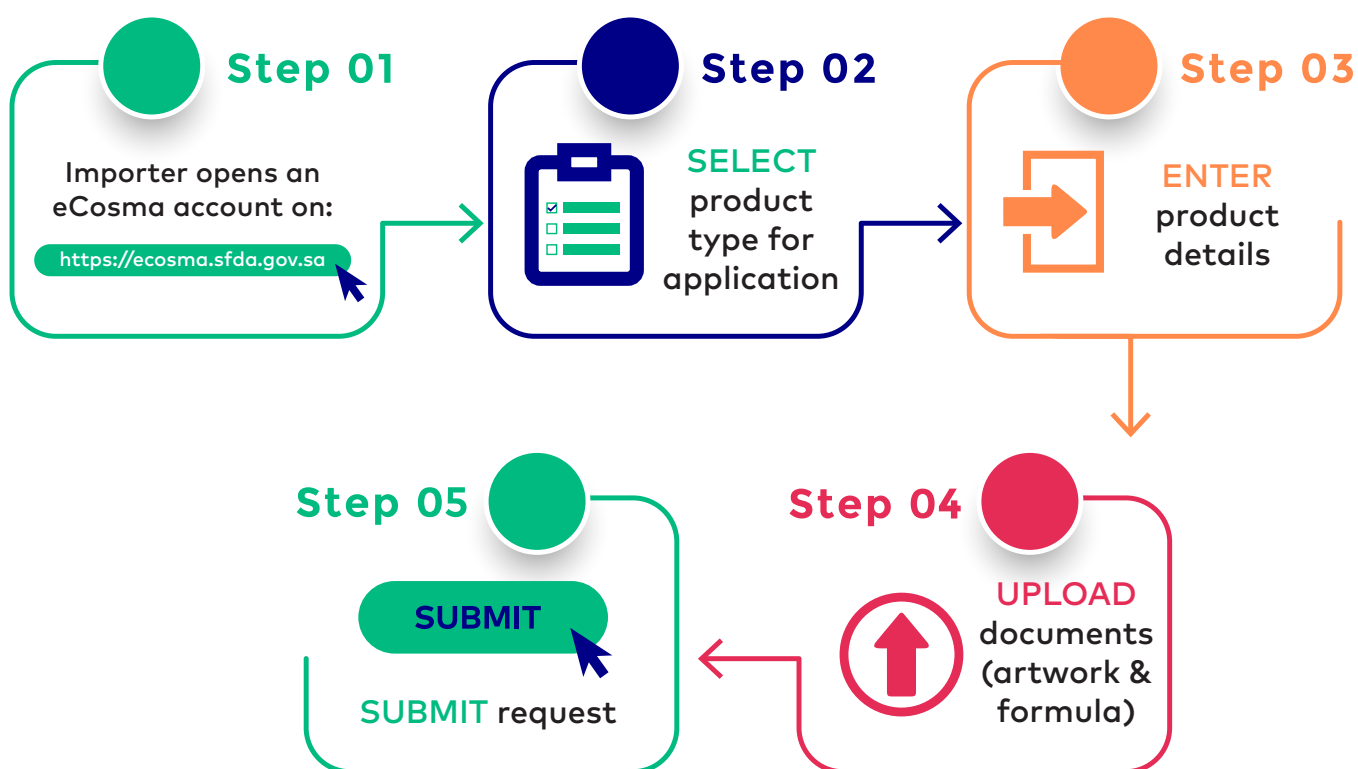
Label artwork should be on a single document.

The ingredients declaration must be uploaded as a formula.

COSMETICS > eCOSMA NOTIFICATION

All cosmetic products should be notified on eCosma. Opening an account is mandatorily initiated by the Saudi importer/distributor, alternatively once the account is opened it is possible to create a sub-eCosma account delegated to a third party such as Cotecna.

ECOSMA REGISTRATION STEPS



A Certificate of Conformity is required for the customs clearance of each shipment. Cosmetic CoCs can only be requested by the importer using the SFDA's FASEH platform: <https://faseh.sfda.gov.sa/en/home>



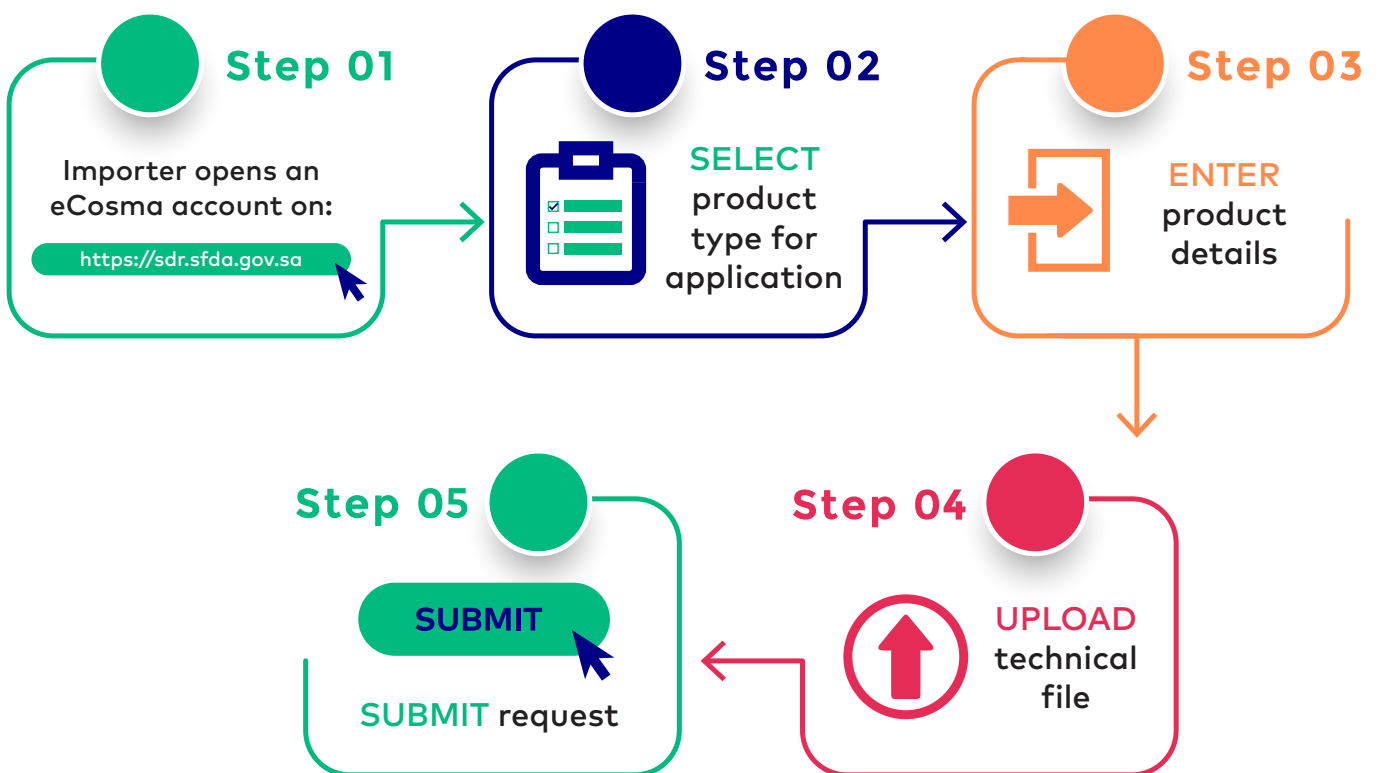
SFDA REGISTRATION PROCESS

REGISTERING WITH SFDA

HEALTH PRODUCTS > SDR REGISTRATION

Health products should be registered on the Saudi Drug Registration (SDR) electronic system. The SDR system aims to facilitate the registration of medicinal, herbal and health products for both human and veterinary use.

SDR REGISTRATION STEPS



Clearance of regulated products is required under IBRCS system (Importing, Batch-Release & Clearance System): <https://ibr.cs.sfda.gov.sa/webpages/common/home.aspx>

3.1 Notes - Rules in the EU

Many countries, including in the EU, loosened their approval process for sanitary products in 2020. The strategic move helped the countries cope with the shortage of these products on the market, also accelerating product access for the general public and health care professionals. The only point of consideration was that the products adhere to the recommended formulas (including EU) and that the levels of alcohol in the formulas were proven to be effective.

4 . CLASSIFICATION

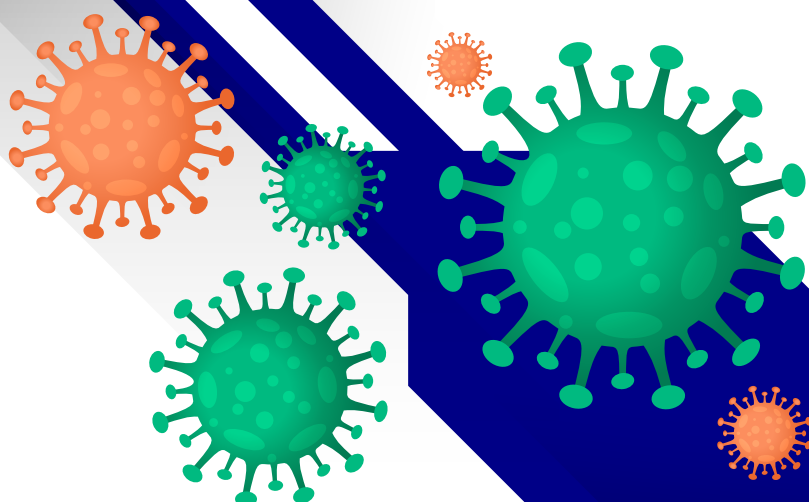


CLASSIFICATION

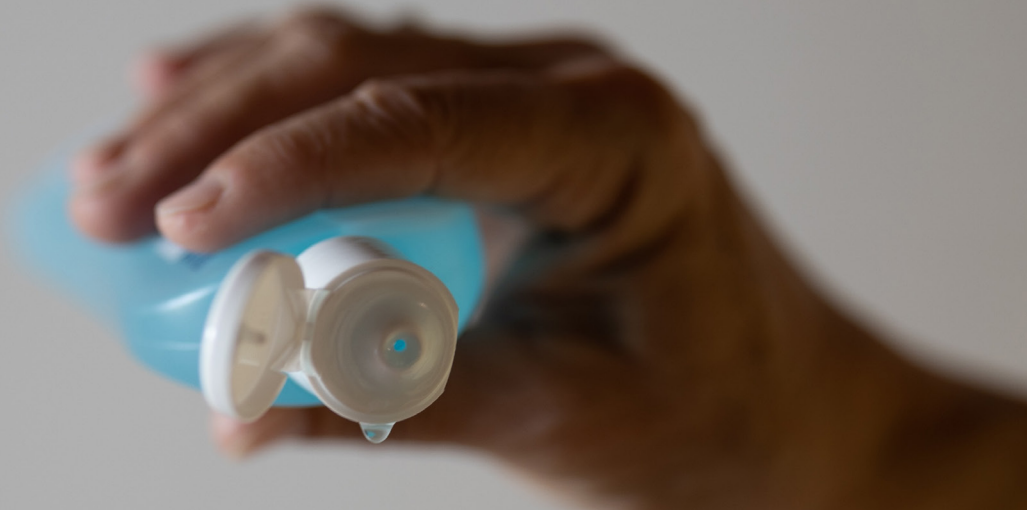
A crucial point to remember is the right product classification and use of the correct application form. This will ensure that you have the correct product dossier and properly align with regulations.

Examples

Hand Gel Differences	
Cleansing Gel Function	Anti-Bacterial Function
No bacterial claims (or as a secondary function "with antibacterial properties")	Claims "disinfectant", "kills bacteria" should be mentioned
Contains alcohol (less than 60%)	Contains alcohol (more than 60%)
Categorized as Cosmetics	Categorized as a Health Product
Not authorized to reference infection, pandemic, disease, COVID-19, etc.	Authorized to reference infection, pandemic, disease, COVID-19, etc.



5. COMPOSITION



COMPOSITION

The main component of a hand sanitizer is alcohol, as well as ethanol and isopropanol.

The rules imposed by the SFDA in Saudi Arabia is that such products must contain the following percentage:

- > Ethanol 60-80% (v/v)
- > Isopropanol 60-70% (v/v)

IMPORTANT

Using the right product classification and application form are critical points for successful regulatory compliance.

5.1 Rules in the EU:

In comparison, European regulators have confirmed four specific active ingredients as being effective enough for use by hand sanitizer manufacturers.

The four approved components allowed by the derogation were ethanol, propanol, chlorine, chlorhexidine, and quaternary ammonium compounds.

6. EFFICACY

EFFICACY

As for any product placed on the market, the efficacy of any claims should be substantiated, and proof of effects are required in the product dossier.

The proof of efficacy is required information for a Health Product Submission, it is required as per Module 5 - "Clinical Study Reports".

This SFDA guideline details the recommended types of evidence to support the safety and efficacy of a herbal and health product submission (Module 5).

6.1 Health Product:

Depending on the nature and status of the health product, sources of acceptable evidence include:

- > **Clinical Studies:** Evidence from clinical studies can provide valuable information about the efficacy and safety of the herbal product. There are several types of clinical studies, including systematic reviews, such as meta-analyses of randomized controlled trial and non-experimental observational studies, such as epidemiological, cohort studies.
- > Regulatory documents e.g. assessment reports and community herbal monograph.

Note 1: Under the cosmetics category, a gel for cleansing hands still has to prove its efficacy.

6.2 Note-Status in the EU

Comparatively, in Europe bacteria killing products are classified as "Biocides" and regulated under EU 528/2012.

Under this regulation, the definition and classification of these products are defined in Annex V. They pertain to the MAIN GROUP 1 "Disinfectants / Product-type 1" defined as: biocidal products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp.

For the EU and to comply with BPR the following standard should be followed:

- > Bactericide activity: EN 13727 (2/1), EN 1500 (2/2)
- > Levuricide activity: EN 13624 (2/1)
- > Turberbucolicide /mycobactericide activity: EN 14348 (2/1)
- > Virucide activity: EN 14476 (2/1)

7. LABELLING



7.1 Labelling Requirements

FOR COSMETICS

General Requirements

1. No graphics, images or phrases that contradict Islamic traditions and prevailing GCC social values.
2. All details should be clearly legible using easily visible lettering
3. Medical claims are prohibited
4. Labelling shall be in Arabic and English
5. All the mentioned markings should be included on both the inner and outer packaging. Except when information is marked with an asterisk (*)

Labelling Requirements

1. Product name and Brand name
2. Product function (unless clear from its presentation) - In Arabic
3. Manufacturer or distributor name and address*
4. Country of origin
5. Net content
6. Product durability
7. Batch number
8. Ingredients list *
9. Conditions of use, warnings, and precautionary statements - In Arabic
10. Any other warning phrases specific to the product and its applications

FOR HEALTH PRODUCTS

All the information below should appear on both the product outer and inner packaging.

1. Name of the medicinal product
2. Statement of active substance
3. List of excipients
4. Pharmaceutical form and contents
5. Method and route(s) of administration
6. Special warning that the medicinal product must be stored out of the sight and reach of children
7. Other special warning(s), if necessary
8. Manufacturing and expiry date (mm/yyyy)
9. Special storage conditions
10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate
11. Manufacturer name
12. Marketing company
13. Name and address of the marketing authorisation holder
14. Marketing authorisation number(s)
15. Batch number
16. General classification for supply
17. Price
18. Datamatrix (2d barcode carrying the unique identifier included)
19. Global trade item number
20. Serial number



7.2 Other related circulars:

The SFDA published a circular in 2015 specific to bacteria-related claims. This circular, n.: 37915 dated 26.11.1436 AH on the **Prevention of Representations of Microbe Control in Cosmetics**, defined what are the acceptable and unacceptable claims on cosmetics products:

- > Representation of microbe and germ control by setting a specific percentage as a control limit or protection. The limit will help show the product efficiency, for instance a 99.9% elimination of germs, bacteria, and so on. However, this is not applicable to cosmetic products.
- > Representations like anti-bacterial, for bacterial protection or helpful in bacterial and virus control, are allowed without setting a certain percentage of microbe control or protection, or making an indication to the product's efficiency in microbe control. These representations are minor, not main representations, and do not indicate that such representations are the main purpose of the product.

Notes

Please use the following precautionary labels:

- > Fire hazard > "flammable" + storage instruction
- > Ingestion > "for external use only" / "keep out of the reach of children"
- > Irritation > do not use on...

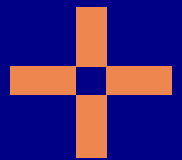


8. PRODUCT RECALLS & RISKS ASSOCIATED WITH THESE PRODUCTS:

Many hand sanitizers were recalled in 2020, and the main risks identified were:

- > **Health risk:** insufficient amount of active matter/alcohol
- > **Health risk:** product contains prohibited ingredients
- > **Burns:** warnings information not labelled
- > **Misuse:** improper labelling*

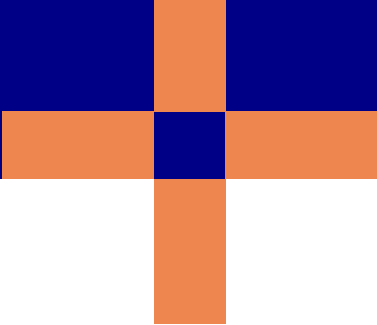
CONCLUSION



As new variants of the COVID-19 virus continue emerging, there seems to be no visible end to the pandemic. As such, cleansing hand gels and sanitizers are more in demand than ever. However, with evolving crisis management and more effective response measures, Saudi Arabia and other countries are beginning to tighten their approval requirements for such products.

To avoid unnecessary product recalls and Customs delays, contact us on info@cotecna.com to learn more about hand sanitizer classification in Saudi Arabia or to get a commitment free quote.





ABOUT SFDA

The Saudi Food and Drug Authority (SFDA) was established under the Council of Ministers resolution as an independent body that directly reports to the President of Council of Ministers.

The main purpose of the SFDA is to ensure the safety of food and drugs for human and animal consumption, of biological and chemical substances, and of electronic products that affect human health, that are being imported into the Kingdom of Saudi Arabia.

About the SFDA Cosmetics Programme

The SFDA Cosmetics Programme is a mandatory conformity assessment programme developed by the SFDA to ensure the quality and safety of cosmetic products imported into the Kingdom of Saudi Arabia.

What are the main purposes of the SFDA programme?

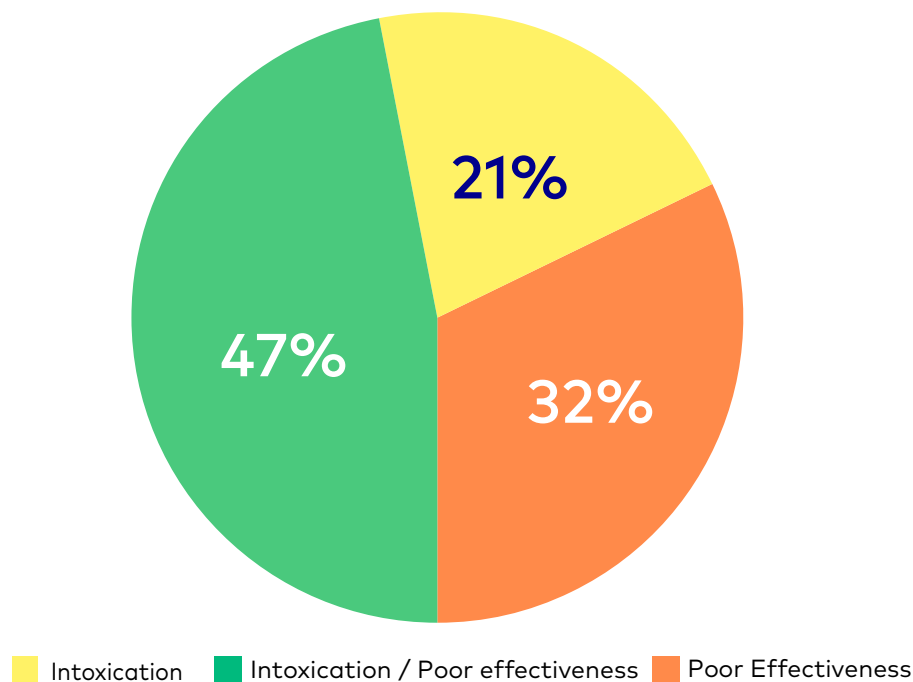
- > To ensure the safety of the products before they are used by consumers
- > The establishment of a global database for all locally imported cosmetic products
- > A clearance authorization for the imported cosmetic products
- > The development of specific standards for cosmetics

ABOUT COTECNA

As a trusted partner of the Kingdom of Saudi Arabia, Cotecna is accredited to help support the SFDA Cosmetics programme and perform the conformity assessment of cosmetic products imported into the country in accordance with all regulations, rules and specifications approved by the SFDA.

+ APPENDIX A

Cases of product misuse and improper labelling:



+ APPENDIX B

Examples of recalls:

- > <https://old.sfda.gov.sa/en/drug/news/Pages/d15-3-2020a1.aspx>
- > <https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/73385a-eng.php>
- > https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/?event=main.search&lng=en
- > <https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-consumers-should-not-use>
- > <https://www.dm.gov.ae/municipality-business/biocides/>

+ REFERENCES

1. **Saudi FDA Products Classification Guidance Version 5.1:**
<https://www.sfda.gov.sa/sites/default/files/2021-10/SFDAProductsClassificationGuidanceE.pdf>
2. **Data Requirement for Herbal & Health Products Submission Version 2.1:**
<https://www.sfda.gov.sa/sites/default/files/2019-06/1561839158%D8%AA%D8%B9%D9%85%D9%8A%D9%85%20%D8%A7%D9%84%D8%A7%D8%AF%D8%B9%D8%A7%D8%A1%D8%A7%D8%AA.pdf>

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