

## GUIDELINES OF IMPORTS FOR THE TRADE

**Saudi Food & Drug Authority**



### KINGDOM OF SAUDI ARABIA

*Saudi Food & Drug Authority Product Conformity Assessment Program*



This data sheet has been prepared specifically in respect of exports to the Kingdom of Saudi Arabia

Date issued : **28/03/2011**

Last modification : **03/03/2020**

### 1. PRODUCT CONFORMITY ASSESSMENT (PCA) MANDATE

PROGRAM NAME

Saudi Food & Drug Authority Product Conformity Assessment Program (New contract)

PROGRAM MANDATED BY

Saudi Food and Drug Authority (SFDA)

IMPLEMENTATION DATE

1<sup>st</sup> January, 2020

PROGRAM OBJECTIVES

Assess and verify compliance of cosmetic products that will be exported to the Kingdom of Saudi Arabia, in accordance with the regulations, rules, specifications and conditions approved by SFDA.

VERIFICATION PROCESS

Exporter submit to SGS the following documents:

- Request for Certification and Declaration of Conformity
- Proforma invoice
- Conformity documents (test reports, ingredient list with concentrations, quality certificates, analysis reports, product labels etc) (Test reports should be from ISO 17025 accredited labs only)
- Company's Quality Management System documents (ISO 9001, GMP certification).
- SFDA Warehouse license.
- Product registration in SFDA electronic system (e-Cosma) - Final Listing Number

ROUTES OF CERTIFICATION

- Route A: Non registered products – this option is considered for infrequent exporters or suppliers. It involves pre-shipment inspection and pre-shipment testing of products. Physical inspection carried out to verify the labelling/markings, storage and other visual verification.
- Route B: Registered products- this option is recommended for regular exporters with homogenous products. Physical inspection is not systematic for registered products and will be carried out at random to assure continuity of compliance. This process involves product testing for compliance and the statement of registration is valid for a year.
- Both routes require a COC for customs clearance for each shipment.

DOCUMENTATION	<p>Based on the documents, SGS will :</p> <ul style="list-style-type: none"> <li>• Verify the conformity of the goods to the applicable SASO standards and requirements</li> <li>• Perform physical inspection of the products (whenever applicable) and, if necessary, take samples for testing.</li> <li>• After verification process completed with satisfactory results; including the physical inspection exporter will have to provide final invoice to allow issuance of these CoC.</li> </ul>
CERTIFICATE	A Certificate of Conformity (CoC) is issued to evidence the compliance of the shipment.
REGULATED HS CODES	Regulated HS codes for cosmetic and personal care products are the ones starting with 3302, 3303 and 3304.

## 2. REGULATED PRODUCTS

### The following product categories are subject to this program:

- Creams, emulsions, lotions, gels and oils for the skin (hands, face, feet , etc).
- Face masks (with the exception of peeling products)
- Tinted bases
- Make up powders, after bath powders, hygienic powders, etc.
- Toilet soaps, deodorant soaps, glycerine soaps etc.
- Perfumes, toilet waters and eau de cologne
- Bath and shower preparations (salts, foams, oils, gels, etc.)
- Depilatories
- Deodorants and anti-perspirants
- 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 ), hair dressing 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 (Mouthwash products containing alcohol are considered as banned products)
- Products for nail care and make up
- Products for external intimate hygiene
- Sun bathing products
- Products for tanning without sun
- Skin- whitening products (except Hydroquinone containing products)
- Anti-wrinkle products
- Eye decorative cosmetic products (eye shadow, mascara, brows, lids, pencil, lashes, cream and athmad (Al Kohl)
- Handwash liquid soaps
- Wet wipes
- Raw Materials for perfumes, cosmetics and Personal care products

## 3. SPECIAL REQUIREMENTS

PROHIBITED IMPORTS	<p>Any cosmetic having lard or lard derivatives is prohibited for import to Saudi Arabia.</p> <p>List of substances that should not be added to cosmetic products are listed out in Annex (2) of GSO 1943/2016 in addition to below:</p> <ul style="list-style-type: none"> <li>• Tretinoin (Retinoic acid) and its salts</li> <li>• Hydroquinone (Dihydroxy Benzene)</li> <li>• Asbestos</li> </ul>
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<p>LABELLING REQUIREMENTS</p>	<p>Marking on the product's package and on outer package shall include the following:</p> <ol style="list-style-type: none"> <li>1. Product name (In Arabic or both Arabic and English)</li> <li>2. The name and address of the manufacturer (either manufacturer or importer)</li> <li>3. The name and address of the agent or the importer in KSA (either manufacturer or importer)</li> <li>4. List of ingredients comprising more than 1% from the overall weight of the products. It should also be listed in descending order according to weight and shall follow the International Nomenclature System (INCI)</li> <li>5. The function of the product unless it is indicated from the way of its presentation (in Arabic or Arabic and English)</li> <li>6. Storage conditions (In Arabic or both Arabic and English)</li> <li>7. Batch number, manufacturing date/ expiry date or production and expiry dates.</li> <li>8. Cautions or precautions (in Arabic or Arabic and English)</li> <li>9. Usage instructions (in Arabic or Arabic and English)</li> <li>10. Period after opening symbol for cosmetics with durability greater than 30 months</li> <li>11. Country of origin as " Made in...."</li> <li>12. Net content in volume or mass (metric system)</li> <li>13. Acceptable cosmetics Claims (if any) (In Arabic or both Arabic and English)</li> <li>14. Non-existence of medical claims (The label on the product shall not contain any medical or therapeutic claims, otherwise it will not be released until it is registered with SFDA as a medicine). Approved Standard for Cosmetics Product Claims: GSO 2528:2016 – Technical Regulation of Cosmetics and Personal Care Product Claims</li> </ol>
<p>PACKING REQUIREMENTS</p>	<ul style="list-style-type: none"> <li>• Cosmetic products of liquid oral hygiene and care products of external parts of genital organs are required to applied to tamper seal these products must contain a label that aware consumers about the presence of tamper seal.</li> <li>• Above are excluding products filled in aerosols.</li> <li>• Optional for other items (for a copy of SFDA circulation related to the above, please contact SGS).</li> </ul>
<p>OTHER SPECIAL REQUIREMENTS</p>	<ul style="list-style-type: none"> <li>• Documents required for clearance: English: <a href="https://www.sfda.gov.sa/en/cosmetic/Pages/product+notification+system.aspx">https://www.sfda.gov.sa/en/cosmetic/Pages/product+notification+system.aspx</a></li> </ul> <p>Note: Please refer to SFDA Guidance for Products Classification (updated to latest version) – <a href="https://www.sfda.gov.sa/en/drug/drug_reg/Pages/default.aspx?catid=5&amp;news=Main">https://www.sfda.gov.sa/en/drug/drug_reg/Pages/default.aspx?catid=5&amp;news=Main</a></p>
<p>SFDA NOTIFICATION PLAN</p>	<p>Starting from 1<sup>st</sup> Feb 2015, SFDA will not clear imported cosmetic products and ingredients for facilities that are not licensed from SFDA. Additionally, it is mandatory to list cosmetic products in ecosma from 1<sup>st</sup> April 2015 based on the attached notification plan. Registration on ECOSMA system should be done by importer For more details you might contact SGS.</p>

	<p>Cosmetic Products Notification System (eCosma):          Note: e-Cosma registration doesn't replace the current requirements for Certificate of Conformity (COC) for shipments to Saudi Arabia. COC will exist along with e-cosma notification process and final listing number will be reflected on CoC against respective product.          Please note that e-cosma registration is free of charge till end of 2018</p>
<p>UPDATES</p>	<p>In line with the above attached 'Guidance for Product Classification', SFDA had released Circulation 7484/A dated 27/3/1432H including the ban of adding Triclosan in all imported or locally manufactured cosmetics products including tooth pastes, and referring to approval of Safety Requirements of Cosmetics Products and Personal Care Regulation Number SFDA.CO/GSO1943:2016 related to banned and restricted ingredients by SFDA Board of Directors in its 15th meeting held on 08-03-1439H (26-Nov-2017) [where the Triclosan was not classified as banned ingredient].</p> <p>SFDA updates the following by attached new amendment- SFDA Circular 35833/A dated 04-05-1440 (11.01.2019):</p> <ul style="list-style-type: none"> <li>• Commencing from 11.01.2019 onward, its allowed to add (Triclosan) to all cosmetic products.</li> <li>• The limits stipulated in the regulation should be followed and adhered to.</li> </ul> <p><b>Circular for LYRAL ban - SFDA</b></p> <ul style="list-style-type: none"> <li>• Referring to the recent reports and published studies about the safety of substance hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC) and know commercially as Lyrall, which is used as scent/perfuming agent in cosmetics, it noticed recently growth of side effect as irritation and skin allergy reaction after using the products containing the substance. Therefore, SFDA have decided after reviewing the evidences and proves:</li> </ul> <p>First: ban the use of (HICC) completely in cosmetics, and that ban also includes below:</p> <ul style="list-style-type: none"> <li>➤ 4-(4-hydroxy-4-methylpentyl)-3-cyclohexene-1-carboxaldehyde</li> <li>➤ 3-(4-hydroxy-4-methylpentyl)-3-cyclohexene-1-carboxaldehyde</li> </ul> <p><b>Second:</b> ban import and/or manufacture violated products starting from <b>1/7/2020</b> and grace period for available products in market till <b>1/7/2021</b>          Most of the products can be easily classified into drug, medical device, cosmetic or food supplement and subsequently identifying which regulation these products should follow to get the marketing authorization. Therefore, the SFDA has developed this document, "Products Classification Guidelines", to help the companies as well as the SFDA regulators to easily classify these products.</p> <p><b>Circular for modification of MIT restriction in cosmetics - SFDA</b></p> <ul style="list-style-type: none"> <li>• Referring to the recent reports and published studies about the safety of methylisothiazolinone which is considered one of the</li> </ul>

preservative in cosmetics, it noticed recently growth of side effect as irritation and skin allergy reaction after using the products containing the substance

Therefore, the authority have decided after reviewing the evidences and proves to modify the restrictions for usage as below:


- **First:** restrict the use of MIT individually of in mixture in rinse off products no more that 0.0015% 15PPM
- **Second:** prohibition of MIT either individually of in mixture for leave on products
- **Thirdly:** cease the addition of MIT to rinse off products which contains ratio CMIT/MIT 3:1
- **Fourthly:** ban import and/or manufacture violated products starting from **1/1/2020** and grace period for available products in market till **31/12/2020**

**Circulars ban on formaldehyde, methylene glycol & restriction of hydrolyzed wheat proteins - SFDA**

- **Formaldehyde** and **methylene glycol** have been banned in all cosmetics products. New imports or manufacturer of products contrary to this circular are hereby prevented from the date: **November 7, 2019**. The timeline to remove existing products form the market will be **24.04.2020**
- Hydrolyzed wheat proteins are now restricted with maximum molecular weight of **3.5 kDa** (3500 Daltons (Da)). New imports or manufacturer of products contrary to this circular are hereby prevented from the issuance date of circular. The timeline to remove existing products form the market will be **14-01-2021**.

**Circular for claim (مسك الطهارة) has been prohibited- SFDA**

- Using the claim Musk Tahara (مسك الطهارة) { "Purity Musk" } and any kind of claims that indicate antiseptic effect in cosmetic products containing musk is now prohibited, in order to prevent any misleading for consumers. All the Musk products in the market that includes this statement will be considered as violation from the date **24-04-2020**.
- Maximum permissible concentration of (Phenylenediamine PPD) and its salts (p-Phenylenediamine HCL) and (p-Phenylenediamine Sulphate) in oxidized hair dyes should not be more than 2%. The use of (p-Phenylenediamine) and its salts is restricted to only oxidized hair dyes. This comes into effect starting **22-06-2020**.
- The use of the ingredient, Diphenylphosphine oxide trimethylbenzoyl to artificial nail products is restricted to 5%. The product identification label must have the following warnings:
  - For professional use only
  - Avoid Skin Contact
  - Read Direction for use carefully
 This comes into effect starting **14-01-2021**.

	<ul style="list-style-type: none"> <li>➤ A list of banned substances (Annex II) in cosmetics manufacturing has been updated in the SFDA website. See below attachement.           <div style="text-align: center;">  <p>Banned List of Ingredients.pdf</p> </div> </li> <li>➤ All ingredients with their INCI names have to be mentioned in Ecosma portal along with individual percentage while registering cosmetic products with SFDA.</li> </ul>
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#### 4. FEES

FEES for COSMETICS				
FOB [USD]		Applicable fee [USD]		
From	To	Of FOB	Min	Max
3000	60,000	210	210	210
60,001	200,000	0.35%	210	600
200,001	600,000	0.30%	600	1500
600,001	1,000,000	0.25%	1500	2000
1,000,001	Or more	0.20%	2000	15000
Government Fees		267 per CoC		

- Where ever Physical Inspection, testing or any other intervension is carried out, SGS rates will be applicable (on actual).
- The government fee is additional to the above mentioned CoC fees.

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