

GUIDELINES OF IMPORTS FOR THE TRADE

Saudi Food & Drug Authority



KINGDOM OF SAUDI ARABIA

*Saudi Food & Drug Authority Product Conformity
Assessment Program for Cosmetics*



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

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1. PRODUCT CONFORMITY ASSESSMENT (PCA) MANDATE

PROGRAM NAME	Saudi Food & Drug Authority Product Conformity Assessment Program
PROGRAM MANDATED BY	Saudi Food and Drug Authority (SFDA)
IMPLEMENTATION DATE	01.01.2020
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.
ASSESSMENT METHODS	Depending on the nature of the product, the assessment methods consist of the following activities: <ul style="list-style-type: none"> • Pre-shipment inspection & Container sealing • Sampling & testing as per SFDA criteria. • Documentary verification
DOCUMENTATION	Exporter submit to SGS the following documents: <ul style="list-style-type: none"> • 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 GHAD portal
ROUTES OF CERTIFICATION	<ul style="list-style-type: none"> • Route A: Non registered products –It involves pre-shipment inspection, testing, loading supervision and container sealing. Physical inspection carried out to verify the labelling/markings, storage, and other visual verification.

VERIFICATION PROCESS	<p>Based on the documents, SGS will :</p> <ul style="list-style-type: none"> • Verify the conformity of the goods to the applicable SFDA/GSO standards and requirements. • Perform physical inspection of the products and, if necessary, take samples for testing from consignment. • After verification process completed with satisfactory results; including the physical inspection exporter will have to provide final invoice to allow issuance of these CoC.
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	
<p>The following product categories are subject to this program:</p> <ul style="list-style-type: none"> • 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, glycerin 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"> • Tretinoin (Retinoic acid) and its salts • Hydroquinone (Dihydroxy Benzene) • Asbestos
LABELLING REQUIREMENTS	<p>Marking on the product's package and on outer package shall include the following:</p> <ol style="list-style-type: none"> 1. Product name (In Arabic or both Arabic and English) 2. The name and address of the manufacturer (either manufacturer or importer) 3. The name and address of the agent or the importer in KSA (either manufacturer or importer)

	<ol style="list-style-type: none"> 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) 5. The function of the product unless it is indicated from the way of its presentation (in Arabic or Arabic and English) 6. Storage conditions (in Arabic or both Arabic and English) 7. Batch number, manufacturing date/ expiry date or production and expiry dates 8. Cautions or precautions (in Arabic or Arabic and English) 9. Usage instructions (in Arabic or Arabic and English) 10. Period after opening symbol for cosmetics with durability greater than 30 months. 11. Country of origin as “Made in. ...” 12. Net content in volume or mass (metric system) 13. Acceptable cosmetics Claims (if any) (in Arabic or both Arabic and English) 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
PACKING REQUIREMENTS	<ul style="list-style-type: none"> • 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. • Above are excluding products filled in aerosols. • Optional for other items (for a copy of SFDA circulation related to the above, please contact SGS).
OTHER SPECIAL REQUIREMENTS	<p>Documents required for clearance: Regulations and Requirements for Import, Clearance and Export</p> <p>Note: Please refer to SFDA Guidance for Products Classification (updated to latest version)</p> <ul style="list-style-type: none"> • Executive Regulations for Cosmetic Products Act <p>Manufacturers and importers of cosmetics products should comply with terms and conditions in Article 21 from the executive regulation for cosmetics related to advertising cosmetics in any traditional media or through social media celebrities either directly or indirectly. In case the authority spotted/found any violation as mentioned above, then shall take proper legal action against the violators adding that the company will bear the responsibilities for the violator advertised content.</p> <p>It is not permissible to advertise or promote any cosmetic products prior to their enrolment. The advertisements and promotions shall be subject to the terms and conditions specified by the regulations: Implementing Regulation of Cosmetic Products Law</p>
SFDA NOTIFICATION PLAN	<p>Starting from 1st 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 GHAD portal. Registration on GHAD portal should be done by importer. For more details you might contact SGS.</p> <p>Note: GHAD registration doesn't replace the current requirements for Certificate of Conformity (CoC) for shipments to Saudi Arabia. CoC will exist along with GHAD notification process and GHAD number will be considered as a mandatory pre-requisite for CoC issuance.</p> <p>Please note that GHAD registration is free of charge till further update from SFDA.</p>

UPDATES

SFDA updates the following by attached new amendment- SFDA Circular 35833/A dated 04-05-1440 (11.01.2019):

- Commencing from 11.01.2019 onward, its allowed to add (Triclosan) to all cosmetic products.
- The limits stipulated in the regulation should be followed and adhered to.

Circular for LYRAL ban - SFDA

- 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:

First: ban the use of (HICC) completely in cosmetics, and that ban also includes below:

- 4-(4-hydroxy-4-methylpentyl)-3-cyclohexene-1-carboxaldehyde
- 3-(4-hydroxy-4-methylpentyl)-3-cyclohexene-1-carboxaldehyde

Second: ban import and/or manufacture violated products starting from **1/7/2020** and grace period for available products in market till **1/7/2021**

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.

Circular for modification of MIT restriction in cosmetics - SFDA

- Referring to the recent reports and published studies about the safety of methylisothiazolinone, which is considered one of the 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 has 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**

	<p>Circulars ban on formaldehyde, methylene glycol & restriction of hydrolyzed wheat proteins - SFDA.</p> <ul style="list-style-type: none"> ➤ 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. <p>Circular for claim (مسك الطهارة) has been prohibited- SFDA.</p> <ul style="list-style-type: none"> ➤ Using the claim Musk Tahara (مسك الطهارة) { "Purity Musk" } and any kind of claims that indicate antiseptic effect in cosmetic products containing muskis 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: <ul style="list-style-type: none"> - For professional use only - Avoid Skin Contact - Read Direction for use carefully This comes into effect starting 14-01-2021. ➤ A list of banned substances (Annex II) in cosmetics manufacturing has been updated in the SFDA website: SFDA Cosmetics Ingredients ➤ All ingredients with their INCI names have to be mentioned in e-Cosma portal along with individual percentage while registering cosmetic products with SFDA.
	<p>Circular on use of the ingredient (MNM) Methyl N-Methyl anthranilate in beauty products</p> <p>Summary: The use of products containing Methyl N-Methyl anthranilate (MNM) causes occurrence of photo-toxicity when exposed to ultraviolet rays from the sun or any other source of ultraviolet radiation.</p> <ul style="list-style-type: none"> ➤ First: Addition of the ingredient Methyl N-Methyl anthranilate (MNM) is prohibited to use in sunscreens products due to direct exposure to sunlight. ➤ Second: It is permitted to use the ingredient Methyl N-methyl anthranilate (MNM) in cosmetic products that remain on the skin (leave-on) with a maximum concentration of 0.1%. <p>This comes into effect starting from 1/1/2022</p>

	<p>Circular on Cosmetic products which look like food.</p> <p>Summary: It has been observed about the appearance of some cosmetic products that are similar in form or packaging with food products is leading to difficulty, amongst children, in differentiating between them as food or cosmetics which may cause a risk on their health.</p> <ul style="list-style-type: none"> ➤ Considering the safety regulations Cosmetic products which look like food requires an additional warning statement on the product either in form or packaging. The cosmetic products referred below must add the statement “KEEP OUT OF REACH OF CHILDREN” in clear writing along with other the warnings mentioned on the label of the product. <p style="text-align: center;">This comes into effect starting from 01/01/2022.</p>
	<p>Update: SFDA FASEH Platform</p> <ul style="list-style-type: none"> ➤ The Saudi Food and Drugs Authority (SFDA) in collaboration with the Saudi customs online platform, FASEH have mandated the upload of certificates issued by the Certification Bodies (CBs) into the platform post 11th July 2021. ➤ Starting 3rd October 2021, all applications for Certificate of Conformity (COC) needs to be submitted by the Importers through FASEH platform. The credentials to be used is the same as their respective e-Cosma accounts.
	<p>Supplementary Circular No. 10551/p regarding banning formaldehyde and methylene glycol in cosmetic products</p> <ul style="list-style-type: none"> ➤ As per the updated circular it is not allowed to use Formaldehyde and Methylene glycol as a raw material in cosmetics products .However regarding the existence of Formaldehyde as an impurity with a limit not more than 0.1% is allowed , if the same is released as a result of the chemical reaction from added preservatives (allowed to be used) which is known to have the property of releasing Formaldehyde. <p>Circular No. 14095 /Adding substances to the list of substances prohibited in cosmetic products.</p> <ul style="list-style-type: none"> ➤ A list of banned substances (Annex II) in cosmetics manufacturing has been updated in the SFDA website. It is prohibited to import or manufacture products that contain one of the ingredients listed in the list from the date of the circular (23.12.2021).
	<p>Update on Musk and Ambergris containing products</p> <p>On May 22, 2022, the Saudi Food and Drug Authority (SFDA) issued the Guide for Cosmetics Containing Musk and Ambergris on the requirements and conditions for manufacturing and trading cosmetics with musk and ambergris in the Kingdom of Saudi Arabia. The Guide, which will come into force on November 2, 2022, specifies the definitions and types of natural musk and natural ambergris, excluding active substances that are chemically prepared to imitate the natural odour of musk and ambergris. The Guide applies to perfumes and cosmetics containing musk or ambergris fragrance extracts.</p>

	<p>SFDA Launch of Unified Electronic System (GHAD) to replace e-Cosma starting from 30th March 2023</p> <ul style="list-style-type: none"> SFDA has announced that, all the services for Licensing and Registration of Cosmetics & Personal Care Products, will be launched through the GHAD system with effect from 30th March 2023. Accordingly, all Saudi Cosmetics & Personal Care Importers and Manufacturers will need to open a commercial account in GHAD notification system instead of e-Cosma and the new applications has to be submitted through GHAD system https://ghad.sfda.gov.sa
	<p>SFDA Update on restrictions of using Azelaic Acid in cosmetic products.</p> <ul style="list-style-type: none"> As per updated Circular (26119 issued on 14 May 2023 AD corresponding to 10/24/1444 AH) "It is allowed to add azelaic acid in all cosmetic products at a percentage not exceeding 15% as a maximum.
	<p>SFDA Update Circular No. 6391 /Adding substances to the list of substances prohibited in cosmetic products.</p> <p>Based on the same, Saudi Food and Drug Authority has decided the following:</p> <ul style="list-style-type: none"> First: All the substances listed in the attached table to this circular shall be added to Annex (2) in the list of substances prohibited for use in the manufacturing of cosmetic products. Second: This decision shall be effective as of January 1, 2024

4. CONTACT INFORMATION

Sithara Hatim
Connectivity & Products - Trade Facilitation Services
 SGS Verification and Conformity Company
 3742 Al Thumamah Rd. Al Yasmeen Dist.
 2nd Floor. Offices 14.
 Riyadh, Saudi Arabia. 13322 - 6493
 Phone: +966 11 2934487
 E-mail: Sithara.Hatim@sgs.com
 Website: www.sgs.com

Vrinda S Nair
Connectivity & Products - Trade Facilitation Services
 SGS Verification and Conformity Company
 3742 Al Thumamah Rd. Al Yasmeen Dist.
 2nd Floor. Offices 14.
 Riyadh, Saudi Arabia. 13322 - 6493
 Phone: +966 11 2934487
 E-mail: Vrinda.Surendran@sgs.com
 Website: www.sgs.com

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