

DATA SHEET

KINGDOM OF SAUDI ARABIA

Verification of Conformity Programme



1. Regulation

Authority:	Saudi Food and Drug Authority (SFDA)
Notification:	DC-2020-0005 issued on 11/02/2020 by the SFDA
Starting date (Renewal):	March 2011 Renewal November 2019
Appointed company(ies):	Certificates shall be issued by companies recognized by SFDA in the country of export such as BUREAU VERITAS (BV)
Scope of the regulation:	Consignment Based Conformity Assessment of cosmetic products to be exported to the Kingdom of Saudi Arabia according to the applicable technical regulations and standards adopted by the SFDA.
Assessment based on:	<ul style="list-style-type: none"> ▪ Documentary review ▪ Control testing if any ▪ Physical inspection if any ▪ Conclusion of the assessment
Remark:	Consignment Based Conformity Assessment for shipments exported from the following countries (Export from other countries is not covered): Australia, Bahrain, Canada, China, Egypt, France, Germany, India, Italy, Lebanon, Poland, Spain, Switzerland, Thailand, Turkey, United Arab Emirates, United Kingdom, United States of America

2. Products subject

Subjected goods:	<p>Cosmetic and Personal Care Products covered by GSO 1943 and the SFDA product classification guidance (https://beta.sfda.gov.sa/en/regulations/65896), mainly the following:</p> <ul style="list-style-type: none"> - Creams, emulsions, lotions, gels & oils for the skin (hands, face, feet etc.) - Face masks (with the exception of peeling products) - Tinted bases (liquids, pastes, powders) - Make-up powders, after-bath powders, hygienic powders etc... - Toilet soaps, deodorant 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: <ul style="list-style-type: none"> o Hair tints and bleaches o Products for waving o Straightening and fixing o Setting products o Cleansing products (lotions, powders, shampoos) o Conditioning products (lotions, creams, oils) o Hairdressing products (lotion, lacquers, brilliantine) - Eye decorative cosmetics (Eye shadow, mascara, brows and lids pencils, lashes cream, eye pencil or eyeliner) - Shaving products (creams, foams, lotions) - Products for making up and removing make-up from the face and eyes - Products intended for application to the lips - Products for care of the teeth and mouth - Products for nail care and make-up - Products for external intimate hygiene - Sunbathing products - Products for tanning without exposure to the sun - Skin whitening products
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– DATA SHEET –

BUREAU VERITAS

	<ul style="list-style-type: none"> - Anti-wrinkle products - Hotel amenities - Cosmetic and personal care products that are supplied in multipacks - Wet wipes
Second-hand goods:	<i>Not acceptable</i>
Prohibited goods:	<i>See Annex 2 of GSO 1943 and the listed products on the SFDA website https://www.sfda.gov.sa/ar/cosmetic/Pages/product+notification+system.aspx</i>
Restricted goods:	<i>See Annex 2 of GSO 1943 and the listed products on the SFDA website https://www.sfda.gov.sa/ar/cosmetic/Pages/product+notification+system.aspx</i>
Counterfeited goods:	<i>Not allowed</i>
Exempted goods:	<i>Please check with the Bureau Veritas Office</i>
Minimum value subject to the programme:	<i>No</i>

3. Technical requirement

Conformity requirements:	<i>Compliance of goods to applicable Saudi technical regulations in addition to national deviations shall be demonstrated with testing and/or conformity documents issued by an accredited entity.</i>
National deviations:	<ul style="list-style-type: none"> - <i>The Country of Origin shall be marked on each product (if the product is too small, it can be accepted on its direct packaging, this is considered on a case by case basis)</i> - <i>The Country of Origin shall not be abbreviated (e.g. "Made in P.R.C." is not accepted it shall be "Made in China" or "Made in the People's Republic of China")</i> - <i>The wording "Assembled in..." shall not be used as marking for the country of origin, "Made in..." shall be used</i> - <i>Labels, markings and instructions shall be legible, well stuck, and not easy to remove</i> - <i>Marking shall not contain depictions that are offensive to the Islamic traditions and social values in the Kingdom Of Saudi Arabia</i>
Labelling requirements:	<ul style="list-style-type: none"> a) <i>Marking shall comply with the requirements of GSO 1943 at least</i> b) <i>Medical claims are not acceptable (if any), claims shall comply with GSO 2528</i>
Other specific requirements (*):	<ul style="list-style-type: none"> - <i>Additional prohibited substances are included in the SFDA circular 16907 from 21/01/2020</i> - <i>Additional prohibited substances are included in the SFDA circular 14095 from 23/12/2021</i> - <i>Methylisothiazolinone (MIT) use is restricted (SFDA circular 62108 from 27/05/2019):</i> <ul style="list-style-type: none"> • <i>MIT shall be used as individual ingredient or mixture with methylchlorisothiazolinone (CMIT) only in "Rinse-Off" products with a maximum of 0.0015% (15ppm)</i> • <i>MIT shall not be used as individual ingredient or mixture with methylchlorisothiazolinone (CMIT) in "Leave-On" products</i> • <i>MIT shall not be added to "Rinse-Off" products already containing a mix of CMIT/MIT with ratio 3:1</i> - <i>Hydroxyisohexyl 3-cyclohexene carboxaldehyde (HICC) commercially known as Lyral use is banned (SFDA circular 66104 from 01/07/2019 amended by circular 1198 from 22/08/2021): Products imported as of July 1st 2022 shall not contain Lyral, the ban also includes both of the following forms of Lyral:</i> <ul style="list-style-type: none"> • <i>4-(4-hydroxy-4-methylpentyl)-3-cyclohexene-1-carboxaldehyde</i> • <i>3-(4-hydroxy-4-methylpentyl)-3-cyclohexene-1-carboxaldehyde</i>

– DATA SHEET –

BUREAU VERITAS

	<ul style="list-style-type: none">- Hydrolyzed Wheat Protein use is restricted: products shall not contain more than 3.5 kDa (3500 Daltons (Da)) (SFDA circular 8350 from 06/11/2019)- Methylene Glycol and Formaldehyde use is banned (SFDA circular 8356 from 06/11/2019): Products shall not contain methylene glycol and/or formaldehyde- Presence of formaldehyde as an impurity, resulting from the decomposition and chemical reactions of some preservatives (allowed to be used) which are known to release formaldehyde (formaldehyde releasers), its limit shall not exceed 0.1% (shall be < 1000 ppm), abiding that adding it as an ingredient is prohibited (SFDA circular 10551 from 18/11/2021)- Trimethylbenzoyl Diphenylphosphine Oxide (TPO) use is restricted (SFDA circular 15922 from 13/01/2020):<ul style="list-style-type: none">• TPO shall only be used in artificial nails and shall not exceed 5%• Warnings on the label shall include:<ul style="list-style-type: none">▪ For professional use only▪ Avoid contact with skin▪ Read directions for use carefully- Para-Phenylenediamine (PPD) and its salts use is restricted (SFDA circular 15923 from 13/01/2020, applicable from June 22nd 2020): p-Phenylenediamine and its salts (p-Phenylenediamine Chloride and p-Phenylenediamine Sulphate) shall be used in oxidized hair dyes only, and shall not exceed 2% as free base- Azelaic Acid use is restricted (SFDA circular 24367 from 08/04/2021, applicable as of January 1st 2022, products in the market shall comply accordingly as of 01/01/2022):<ul style="list-style-type: none">• Azelaic Acid shall not exceed 0.3% in leave-on products (products that stay on the skin)• Azelaic Acid shall not exceed 10% in rinse-off products (products that can be rinsed off the skin)- Methyl N-Methylantranilate (MNM) use is restricted (SFDA circular 24366 from 08/04/2021, applicable as of January 1st 2022, products in the market shall comply accordingly as of 01/01/2022):<ul style="list-style-type: none">• Methyl N-Methylantranilate (MNM) is banned in sunscreen products, sunscreen products shall not contain MNM• Methyl N-Methylantranilate (MNM) shall not exceed 0.1% in Leave-on products (products that stay on the skin)- <u>Additional requirements on Methyl N-Methylantranilate (MNM) as per SFDA circular 30731 from 28/07/2022, applicable as of 01/07/2023:</u><ul style="list-style-type: none">• <u>Methyl N-Methylantranilate (MNM) can be added to Rinse-off products and shall not exceed 0.2%</u>• <u>Below restrictions shall be followed for the use of Methyl N-Methylantranilate (MNM):</u><ul style="list-style-type: none">- Do not use with nitrosating agents- Maximum nitrosamine content: 50µg/Kg- Keep in nitrite-free containers- Cosmetic products that resemble or look like food products in their packing or form (e.g. soaps, or peeling products, etc), shall contain the expression “Keep Out of Reach of Children” or the like on the product and/or its direct retail labelling SFDA circular 24369 from 08/04/2021, applicable as of January 1st 2022, products in the market shall comply accordingly as of 01/01/2022.- Addition of Titanium Dioxide to the list of restricted ingredients as per circular 615 from 15/08/2021 as follows:<ol style="list-style-type: none">1. Addition of Titanium dioxide to the list of restricted ingredients of cosmetic products as per the restrictions stipulated in Annex 1 of the circular.2. Amendment of the Titanium Dioxide permitted content in the list of allowed colorants in cosmetic products as per the restrictions in Annex 2 of the circular.3. Amendment of the Titanium Dioxide permitted content in the list of UV filters in cosmetic products as per the restrictions in Annex 3 of the circular.
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– DATA SHEET –

BUREAU VERITAS

	<p><i>This circular is applicable from January 1st 2022 for products entering Saudi Arabia (no cosmetic product is allowed after this date if it doesn't comply with this circular) and from January 1st 2023 for products already in the Saudi Market.</i></p> <p>Link to circular: https://beta.sfda.gov.sa/sites/default/files/2021-08/TitaniumDioxide.pdf</p> <p>- <i>Products in metal aerosol cans shall also comply with SASO 1228</i></p>
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4. Application

Applicant:	<i>Any supplier</i>
Application name:	<i>Request for certificate (RFC)</i>
Required documents:	<ul style="list-style-type: none"> • <i>Request for Certificate (RFC),</i> • <i>Copy of final invoice is required, pro-forma is acceptable to open the file only, and contain at least the following:</i> <ul style="list-style-type: none"> ▪ <i>Name of the manufacturer and nationality/origin</i> ▪ <i>Number of the invoice and date</i> ▪ <i>Name of the product</i> ▪ <i>Batch number or lot number or production date</i> • <i>Proof of an implemented Quality Management System (e.g. quality documents, certificates ISO 9001, GMP, ISO 22716, etc...)</i> • <i>Conformity documents (issued by an ISO/IEC 17025 accredited entity or laboratory)</i> • <i>Declaration of conformity (Please check with the Bureau Veritas Office for a template copy)</i> • <i>Valid eCosma registration number or notification</i> • <i>List of ingredients with concentrations (concentrations are only required to verify restricted products content)</i>
Required information:	<ul style="list-style-type: none"> • <i>HS code as per the Saudi tariff code (optional)</i> • <i>Batch or lot number or production date of each line item</i>
Application office(s):	<i>Bureau Veritas offices (see contacts list on Verigates):</i> https://verigates.bureauveritas.com/programmes/saudi-arabia

5. Control testing requirements

Applicable cases:	<i>Conformity document not available or not acceptable</i>
Laboratory criteria:	<i>ISO/IEC 17025 accredited laboratory</i>
Testing:	<i>Control testing according to the applicable Saudi national standards and technical regulations</i>

6. Physical inspection requirements

Scope of inspection:	<i>Review of markings as per applicable standard(s) and identification of products</i>
Destination inspection:	<i>Not allowed</i>
Witness of loading:	<i>Not mandatory</i>

– DATA SHEET –

BUREAU VERITAS

Seal of container/stamping/tape sealing of products:	<i>Not mandatory</i>
Sampling:	<i>In case of control testing (see section 5 as above)</i>
Type of report issued:	<i>Inspection report (IR)</i>

7. Facilitation procedures

The documents and system already in place to ensure conformity to Saudi requirements are preliminarily reviewed (test report, certificate, results of testing, inspection, conformity procedure ...).

8. Conclusion of the Assessment

- *Certificate of Conformity (CoC)*
- *Non Conformity Report (NCR)*

9. Fees

Inspections are paid by the Exporters directly to Bureau Veritas Office handling the file.

Inspections and testing may be charged based on the location and type of assessment when needed

Fee structure is available at the local Bureau Veritas office.

10. Contact

See contacts sheet for details on Verigates: <https://verigates.bureauveritas.com/programmes/saudi-arabia>

11. Other relevant information

N/A

() updated information*

The information contained herein is for the purpose of facilitating conformity assessment procedures and does not relieve Exporters or Importers from their obligations in respect of compliance with the import regulations of the country of importation. Although every effort has been made to ensure the correctness of the information, as at the date of issuance of this data sheet, Bureau Veritas does not accept any responsibility for errors or omissions and, furthermore, the information may subsequently be subject to change as may be announced by the Authorities in the country of importation. Consequently, Exporters are advised to check with Bureau Veritas, prior to shipment of the goods, if there is any doubt concerning the issuance of a Certificate of Conformity.