

**CENTRAL DRUGS STANDARD CONTROL
ORGANIZATION
(Cosmetics Division)**

Frequently Asked Questions

on

**Registration and Import of Cosmetics into
India**

(The Cosmetics Rules, 2020 vide GSR.No.763 (E) dated 15.12.2020)



**CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
DIRECTORATE GENERAL OF HEALTH SERVICES
MINISTRY OF HEALTH AND FAMILY WELFARE
(GOVERNMENT OF INDIA)**

Notice:

The replies to the FAQs are aimed only for creating public awareness about regulation on import of cosmetics by CDSCO and are not meant to be used for any legal or professional purposes. The readers are advised to refer to the statutory provisions of the Drugs and Cosmetics Act, 1940 & Rules made there under and respective Guidelines/Clarifications issued by CDSCO from time to time for all their professional needs.

Frequently Asked Questions on Registration and Import of Cosmetics into India

Q.1 What is a Cosmetic in India?

Ans: As per Section 3(aaa) of the Drugs and Cosmetics Act, 1940, Cosmetic means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance and includes any article intended for use as a component of cosmetic.

Q.2 Whether import of Cosmetic is regulated in India?

Ans: Yes, import of cosmetic is regulated in India under the provisions of the Drugs & Cosmetic Act, 1940 & the Cosmetics Rules, 2020.

Q.3 Where can we get a copy of the Gazette notification G.S.R 763 (E) i.e. the Cosmetics Rules, 2020?

Ans: The copy of the Cosmetics Rules, 2020 is available under Cosmetics Section on CDSCO website ([Gazette notification G.S.R 763 \(E\)](#)).

Q.4 What is the purpose of regulating import of cosmetics in India?

Ans: Import of cosmetics in India needs to be regulated to ensure safety, quality and performance of cosmetics being imported into India.

Q.5 Where can we get a copy of the Drugs & Cosmetics Act, 1940 & the Cosmetics Rules, 2020?

Ans: The copy of the Drugs & Cosmetics Act, 1940 & the Cosmetics Rules, 2020 is available on [CDSCO website](#).

Q.6 Who can import cosmetics into India?

Ans: The manufacturer himself/the Authorized Agent of the Manufacturer/the authorized subsidiary of the manufacturer in India/any other importer in India can be an applicant for grant of Import Registration Certificate for import of cosmetics products into India.

Q.7 What is Import Registration Certificate?

Ans: Import registration certificate” means a certificate issued under rule 13 of New Cosmetics Rules, 2020 by the Central Licensing Authority for registration of cosmetics manufactured for import into and use in India.

Q.8 Which is the Regulatory Authority that governs the regulations of import of Cosmetics into India?

Ans: The Drugs Controller General (India), Central Drugs Standard Control Organization (CDSCO)HQ, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India , FDA Bhawan, ITO, Kotla Road, New Delhi -110002 Phone: 91-11- 23236965 / 23236975, Fax: 91-11-23236973, E-mail:- dci@nic.in.

Q.9 Which division of CDSCO (HQ) is responsible for registration of Cosmetics for import into India?

Ans: Cosmetics Division, Central Drugs Standard Control Organization (CDSCO) HQ,

Q.10 What are the requirements for import of Cosmetics into India?

Ans: For import of Cosmetics products into India, the cosmetic products and manufacturing site are to be registered with Central Drugs Standards Control Organization by submitting an application in Form COS-1 to obtain a Registration Certificate in Form COS-2.

Q.11 What is Form COS-1?

Ans: Form COS-1 is an application for grant of a Registration Certificate for Import of cosmetics into India under the Cosmetics Rules, 2020.

Q.12 What is Form COS-2?

Ans: Form COS-2 is an Import Registration Certificate to be issued for import of cosmetics into India under the Cosmetics Rules, 2020.

Q.13 What is the procedure to obtain a “Import Registration Certificate” in Form COS-2 for import of cosmetics into India?

Ans: A detailed procedure to obtain “Import Registration Certificate” in Form COS-2 is available under [Cosmetics Section on CDSCO website](#).

Q.14 What are the documents required for issuance of Registration Certificate in Form COS-2?

Ans: Documents required for issuance of Import Registration Certificate in Form COS-2 are available under Cosmetics Section on [CDSCO website](#). *(Detailed information is available under the Guidance Document on CDSCO website.*

Q.15 What is the fee required for registration of cosmetics for import into India?

Ans: As per the Third Schedule of Cosmetics Rules, 2020, a fee of One Thousand US dollars or its equivalent in Indian Rupees for grant or retention of Registration Certificate for each category of cosmetics, a fee of Five Hundred US dollars for registration of each manufacturing site, a fee of Fifty US dollars for each variant and a fee of One Thousand US dollars for grant or retention of Registration Certificate for additional category of Cosmetic shall be paid along with the application in Form COS-1.

Q.16 How the fees shall be paid for registration of cosmetics for import into India?

Ans: As per the circular no. [CDSCO/IT/2018-\(37\) dated 09.01.2019](#) of this directorate, from 15.02.2019 the fees shall be paid through Bharatkosh only. The fee shall be paid through Bharatkosh gateway under Head of Account “0210041040000-00-1” Import and Registration and the acknowledgement receipt shall be submitted along with the application for registration of cosmetics.

Q.17 Under which category(s), cosmetics are required to be classified while applying for Registration Certificate for import into India?

Ans: Cosmetics are categorized as per Fourth Schedule of the Cosmetics Rules, 2020 while applying for Registration Certificate for import into India?

Q.18 What is a variant in respect of import registration of Cosmetics?

Ans. Different colour/shade or flavour of a product can be considered as a variant for the purpose of registration for import of cosmetics into the country.

Q.19 What is “use before” or “date of expiry”?

Ans. “Use before” or “date of expiry” means the date recorded on the container, label or wrapper as the date up to which the cosmetic shall retain its characteristics as per standard at proposed storage condition stated on the label.

Q.20 What is actual manufacturer?

Ans. Actual manufacturer in relation to import of cosmetics, means a person who manufactures cosmetics at his own manufacturing site in a country other than India approved by National Regulatory Authority or any authorized competent authority in that country for that purpose, by whatever name called.

Q.21 What is legal manufacturer or brand owner?

Ans. Legal manufacturer or brand owner in relation to import of cosmetics, means a person, who authorise the other manufacturer from India or overseas countries for the manufacture of cosmetics, by way of an authorization referred under Rule 12 of the Cosmetics Rules, 2020.

Q.22 How can someone import cosmetic if it is already registered under Rule 13 of the Cosmetics Rules, 2020 for import into India?

Ans. A cosmetic manufactured at a foreign site and already registered under Rule 13 for import and sale in India, may be imported by any person or entity by making an online application in Form COS-4 for grant of Import Registration Number in Form COS-4A in SUGAM Portal with an undertaking as specified in Sixth Schedule.

Q.23 What is the validity of Import Registration Number issued in Form COS-4A under rule 17 of the Cosmetics Rules, 2020?

Ans. An Import Registration Number granted in Form COS-4A shall remain valid for a period of three years from the date of its issue, unless it is suspended or cancelled.

Q.24. To whom shall an application be submitted for grant of Import Registration Number for import of cosmetics which is already registered for import into India?

Ans. The applications for grant of Import Registration Number for import of cosmetic which is already registered for import into India shall be submitted to the Drugs Controller General (India), Central Drugs Standard Control Organization (CDSCO)HQ, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, FDA Bhawan, ITO, Kotla Road, New Delhi -110002.

Q.25 What is the time period for grant of Registration Certificate in Form COS-2?

Ans: As per Rule 13 of the Cosmetics Rules, 2020, if the application is complete in all respects and information and documents specified in Part I of Second Schedule is in order, the Central Licensing Authority may, on being satisfied, grant Import Registration Certificate or may reject such application for which reasons shall be recorded in writing within a period of six months from the date an application. However, CDSCO's targeted timeline for processing of applications is 90 days as per Circular dated 30.05.2014.

Q.26 What is the duration/validity of "Registration Certificate" in Form COS-2 for import of Cosmetics into India?

Ans: A Registration Certificate in Form COS-2 shall remain valid in perpetuity, subject to payment of registration certificate retention fee specified in the Third Schedule before completion of the period of Five Years from the date of its issue, unless it is suspended, or cancelled by the Central Licensing Authority.

If the licensee fails to pay the required registration certificate retention fee on or before the due date, the registration certificate holder shall, in addition to the registration certificate retention fee, be liable to pay a late fee calculated at the rate of two per cent. of the registration certificate retention fee for every month or part thereof within one hundred and eighty days and in the event of non-payment of such fee during that period, the registration certificate shall be deemed to have been cancelled.

Q.27 How to register additional product(s)/manufacturing site in the already granted/valid Registration Certificate in Form COS-2?

Ans. Importer has to apply for endorsement to the existing valid Registration Certificate along with the requisite documents except fees if the category is already registered and provided that the additional product(s) are being manufactured at the same manufacturing site. If additional category needs to be added, a fee of USD 1000 for each additional category needs to be paid. If an additional manufacturing site has to be added in the endorsement then a fee of USD 500 needs to be paid for registration of each additional manufacturing site.

Q.28 What will be the duration/validity of endorsement issued under valid Registration Certificate in Form COS-2 for additional products?

Ans. Duration/validity of endorsement will be same as of the Registration Certificate (Form COS-2) under which endorsement has been issued.

Q.29 What are the additional documents are required to be submitted for import of cosmetics in bulk finished formulation ready to fill?

Ans. A valid manufacturing license for finished formulation of cosmetic ready to fill in finished form from the State Licensing Authority and details of registered brand owner of the finished product in India need to be submitted along with application in Form COS-1. However, in case of trader or other importer who do not have their own manufacturing site but they only supply to the manufacturer having valid manufacturing license. Such applicant

needs to submit a notarized agreement with the manufacturer along with copy of valid manufacturing license of that manufacturer. The details of registered brand owner of the finished product in India also need to be submitted.

Q.30 What is New Cosmetic?

Ans. A cosmetic which contain novel ingredient which has not been used anywhere in the world or is not recognised for use in cosmetics in any National and International literature.

Q.31 Is prior permission required for import or manufacture of New Cosmetics in India?

Ans. Yes. Prior permission from the Central Licensing Authority is required for import or manufacture of New Cosmetics in India.

Q.32 What is procedure for prior permission for import or manufacture of New Cosmetics in India?

Ans. The applicant shall obtain a prior permission in Form COS-3, by making an application (in offline mode) in Form COS-12 along with requisite fee and documents as provided in Chapter V of the Cosmetics Rules, 2020, from Central Licensing Authority before registration of import of new cosmetic in India.

Q.33 What is procedure for import or manufacture of New Cosmetics in India?

Ans. An application for import and manufacture under Chapter III and under Chapter IV respectively, of the Cosmetics Rules, 2020 shall be made to the Central Licensing Authority or the State Licensing Authority, as the case may be, along with the prior permission obtained in Form COS-3 from the Central Licensing Authority.

Q.34 Whether Cosmetic products, having a valid Registration Certificate, can be imported from any notified ports of India?

Ans. Yes.

Q.35 Who can issue free sale certificate for import of Cosmetic products?

Ans. Free sale certificate can be issued by the National Regulatory Authority which in Original or authenticated (notarized/apostilled/attested by Indian Embassy) from Country of origin is required to be submitted. In case if it is not issued by National Regulatory Authority from the country of origin then from other competent Associations/ organizations duly authenticated from the Indian embassy of country of origin need to be submitted or in case if free sale certificate is authenticated either from chamber of commerce and apostilled or from notary public and apostilled, then it may be accepted.

Q.36 Is it required to submit free sale certificate for all variants of the Cosmetic products to be imported?

Ans. Yes. Free sale certificate for all variants needs to be submitted.

Q.37 Is authentication required for the document “Authorization From Manufacturer”?

Ans. Yes, an authorization by the manufacturer to his agent in India shall be duly authenticated either in India before a First Class Magistrate or by Indian Embassy in the country of origin or by an equivalent authority through apostile.

Q.38 What changes on granted Registration Certificate require an applicant to make a fresh registration?

Ans. The following changes require a fresh registration –Any change in constitution of a registration holder or overseas manufacturer. An application shall be made under Rule 12 for grant of fresh Registration with in a period of 180 days from the date of such change in constitution.

Q.39 What are the changes which do not require fresh registration and only notification or amendment may be obtained?

Ans. For any changes in product labelling or composition or testing of registered cosmetic product or its specification, the Central Licensing Authority shall be informed within 15 days along with an undertaking that registered cosmetic products comply with BIS as referred in the Ninth schedule.

Any change in name or address of Registration Certificate (RC) holder or Overseas Manufacturer, an application for amendment shall be made in online portal for prior approval of Central Licensing Authority (CLA) for the said changes in registration certificate with in a period of 60 days from the date of such changes.

Q.40 Any changes in name and/or address of Indian agent/ Importer/ legal and/or actual manufacturer or change in constitution after issue of Registration Certificate are required to be communicated to the Licensing Authority?

Ans., Yes, as per condition nos. 3, 4& 5 of the Form COS-2.

Q.41 Whether acquisition/merger of one company by another company is considered as change in constitution of the company?

Ans. Yes and Indian agent/ Importer shall inform the licensing authority immediately in writing and shall submit fresh application as per as per condition 4 of Form COS-2.

Q.42 What is voluntary recall of cosmetics?

Ans. If a manufacturer or authorized agent, as the case may be has reason to believe that a cosmetics, which has been imported, manufactured, sold or distributed, is likely to pose risk to health of a user and therefore may be unsafe, such manufacturer or authorized agent shall immediately initiate procedures to withdraw the said product from the market under intimation to concerned SLA or CLA, as the case may be, of the details relating thereto.

Q.43 Whether original labels are required to be submitted to CDSCO at the time of application for registration of Cosmetics?

Ans. While original labels are required, however applicants may submit copy of original label incorporating all details as per chapter VI of Cosmetics Rules, 2020.

Q.44 What are the labelling requirements to be complied for importing cosmetics into India?

Ans: Label should be in conformity with Rule 34 read with Chapter VI of the Cosmetics Rules, 2020.

Q.45 Can the importers of registered Cosmetic products incorporate India-specific requirements on labels after/post landing in India at customs warehouse or place approved by the Licensing Authority?

Ans. Yes, importers of registered Cosmetic products are currently allowed to incorporate India specific requirements like name and address of importer, import Registration Certificate Number on imported Cosmetic products post landing in India at the bonded warehouses.

Q.46 If applicant has applied for Registration Certificate and still not issued but in between there is the change has happened in the constitution of either Manufacturer or Indian Agent, address of manufacturer whether fresh fees is required for product registration?

Ans. No. The applicant has to submit the Fresh application excluding fee.

Q.47 What is the time limit for submission of Query Response?

Ans. There is no time limit for submission of Query Response as per the provision of Drugs and Cosmetics Act, 1940 and Cosmetics Rules, 2020; however, it should be reasonable and justifiable.

Q.48 Can Third party/Authorized Consultant asks the status of the application?

Ans. No. either applicant or his authorized Regular employee may ask the status of their application if it is beyond the time limit prescribed under Drugs and Cosmetics Act, 1940 and the Cosmetics Rules, 2020.

Q.49 Who is authorized to make a Technical Presentation, on behalf of applicant/firm, when asked by the CDSCO?

Ans. Only authorised Subject Expert or Technical Person of the firm/company, who is competent to make technical presentation.

Q.50 Is registration certificate required for importing small quantities of Cosmetic products for R&D purposes like packaging trials, consumer studies, shelf life studies and transport studies?

Ans: No, Registration Certificate is not required.

Q.51 Where do we approach to get No objection certificate for import of Cosmetic products for R&D purposes like packaging trials, consumer studies, shelf life studies and transport studies?

Ans. Concerned Port offices of CDSCO are required to be approached for the above mentioned purposes.

Q.52 Whether Registration Certificate is required for import of Cosmetic products in bulk for repackaging for 100% export to other countries?

Ans. No, Registration Certificate is not required. In such cases the importer has to obtain necessary permission from CDSCO, HQ New Delhi. Importer must give a written undertaking stating that these products are not released for domestic sale.

Q.53 What supporting documents do I need to submit to comply Rule 18(4) with respect to ban on animal testing on imported cosmetics?

Ans. At the time of clearance of the consignment at the port office, an undertaking issued from the manufacturer stating that the cosmetic has not been tested on animals on 12.11.2014 or after the date is required to be submitted to the concerned port office. (as per circular, file no. 18- 12/2013-DC/part file dated 03.02.2015)

Q.54 Whether cosmetic with any drug claim on label/literature can be considered for registration as cosmetic?

Ans. No. Cosmetic and Drug are defined separately under Section 3 of the Drugs and Cosmetics Act, 1940. Products having drug claim do not come under the definition of cosmetic as per the Act and therefore cannot be considered for registration as cosmetic. Further, No cosmetic may purport or claim to purport or convey any idea which is false or misleading to the intending user. [As per rule 36 of the Cosmetic Rules, 2020]

Q.55 Whether cosmetics tested on animals in country of origin are allowed for import in India?

Ans. No, cosmetics that are tested on animals are not allowed for import in India.

Q.56. Which standards to comply for cosmetic products?

Ans: No cosmetic shall be imported unless it complies with the standards prescribed under Ninth Schedule of the Cosmetics Rules, 2020 or any other standards of quality and safety, applicable to it, and other provisions under the Rules. In case the cosmetic is not included under Ninth Schedule, it shall meet with specifications under the rules and standards applicable to it in the country of origin.

Q.57 Is Certificate of Analysis (COA) necessary to submit for grant of registration certificate?

Ans: No, it is not necessary. However, manufacturer may submit this document in place of product specification.

Q.58 Whether percentage composition of cosmetics products is required for registration?

Ans. Yes, as per clause 3(a) of Part 1 of Cosmetics Rules, 2020, name(s) of ingredients in the nomenclature of standard references, along with percentage contained in the cosmetics is required to be submitted.

Q.59 Does CDSCO grant license to manufacture cosmetics in India?

Ans: No, CDSCO does not grant license to manufacture cosmetics in India.

Q.60 Who issues the manufacturing license for cosmetics in India?

Ans: Manufacturing license for cosmetics are issued by respective State Licensing Authorities appointed by State Governments.

Q.61. Whether details of principal manufacturer and actual manufacturer are required on the labels of imported cosmetic?

Ans. As per Chapter VI, Rule 34 if the product has not been manufactured in a factory owned by the manufacturer, the name and address of the actual manufacturer or name of the country where it has actually been manufactured as “Made in.....(Name of country)” should be there on the label. Further, for very small size container where the address of the manufacturer cannot be given, the name of the manufacturer and his principal place of manufacture shall be given along with pin code.

Q.62 Whether breakdown of perfume/parfum/fragrance in composition of cosmetic product is required?

Ans. As per IS 4707 (Part 2):2017, the presence of the substance must be indicated in the list of ingredients when its concentration exceeds.- a) 0.001% in leave on products b)0.01% in rinse off products. Besides that some fragrance ingredients are mentioned in ANNEX-A (list of substances which must not form part of the composition of the cosmetic products)

However, firm may submit undertaking from the manufacturer stating that the perfume/parfum/fragrance compositions are free from banned fragrance ingredients and complying to IS 4707 (Part 2):2017.

Q.63 How can the firm apply for post approval change in the already issued Registration Certificate in Form COS-2?

Ans. Firm can apply online on [SUGAM portal of CDSCO](#) w.r.t. the post approval change in their already issued/valid Registration Certificate.

Q.64 What are the post approval changes for which the firm can apply online on SUGAM portal of CDSCO?

Ans. Firm can apply online for the below mentioned post approval changes in their already issued Registration Certificate:-

- i. Change of the Indian Agent in Registration Certificate (without constitution change)

- ii. Change of Name of legal/principal manufacturer in Registration Certificate (without constitution change)
- iii. Change of address of legal/principal manufacturer in Registration Certificate (Location Change)
- iv. Change of address of legal/principal manufacturer in Registration Certificate (No Location Change)

Q.65 What is a variant in respect of import registration of Cosmetics?

Ans. Different colour/shade or flavour of a product can be considered as a variant for the purpose of registration for import of cosmetics into the country.

Q.66 Whether different pack size of a product falls under the definition of variant?

Ans. No. As per the Form COS-1 and Part 1 of Second Schedule, it is required to mention the name of cosmetics along with their brand name, category, pack size and variants to be registered and meant for import into and use in India. Similarly, under Registration Certificate in Form COS-2, it is also required to mention the pack size and variant separately. Therefore, different pack size(s) of a product are not covered under the definition of variant.

Q.67 For import of which category of cosmetics, import registration certificate is not required?

Ans. The following categories of cosmetics can be imported without import registration certificate subject to condition that the cosmetics shall not be used for domestic sale:-

- (i) Cosmetics in bulk for repackaging for 100% export to other countries.
- (ii) Cosmetics for research and development purposes like packaging trials, consumer studies, shelf life studies and transport studies.
- (iii) Cosmetics for sale to overseas passengers in duty free shops situated within international airports.
- (iv) Cosmetics in amenity kits for exclusive use of International passengers on complimentary basis if not be used for domestic sale.
- (v) Cosmetics imported for use in hotels exclusively for their captive consumption and after providing notarized undertaking to this effect.
- (vi) Hair Fixers, namely mucilaginous preparations containing gums, used by men for fixing beard.

Q.68 I want to import already registered cosmetics in the form of single Kit(s) and the individual products of that Kit(s) are already registered under the Cosmetics Rules, 2020. Whether import of such Kit(s) need a Registration Certificate for import into India or not?

Ans. No. Cosmetics imported in the form of a Kit to be marketed in India as such, wherein all individual products of the Kit are already registered for import into India under Cosmetics Rules, 2020, such Kit is exempted from registration. However, if the applicant opted for registration certificate for kit, the same may be granted without any fees.

Q.69 If I am having a valid registration certificate issued prior to the implementation of the Cosmetics Rules, 2020 and now I want to import already registered cosmetics in the form of Kits. Whether import of such Kit(s) need a registration certificate for import into India or not?

Ans. Yes. Only such cosmetics imported in the form of Kit(s) to be marketed in India as such are exempted from registrations which are already registered for import into India under the Cosmetics Rules, 2020.

Q.70 If I am having a valid Registration Certificate (Form 43) issued prior to the implementation of the Cosmetics Rules, 2020, can I endorse other new products/pack size or manufacturing site in my old valid Registration Certificate (Form 43) after commencement of the Cosmetics Rules, 2020?

Ans. No. After commencement of the Cosmetics Rules, 2020 i.e. after 15.12.2020, the firm need to apply for a fresh Registration Certificate for import of cosmetics into India under the provisions of the Cosmetics Rules, 2020. However, the old Registration Certificate (Form 43) granted under the Drugs and Cosmetics Rules, 1945 is valid for import of cosmetics registered in that Registration Certificate till its expiry or for a period of eighteen months from the date on these rules are notified, whichever is later.

Q.71 What will be the status of the application for grant of registration certificate which are applied before 15.12.2020 but are still in process and not granted the registration certificate?

Ans. The applications for grant of registration certificate which are applied before 15.12.2020 under the Drugs and Cosmetics Rules, 1945, but are still in process/query reply not submitted and not granted the Registration Certificate, such applications will be processed as per the Drugs and Cosmetics Rules, 1945.

Q.72 Will the old Registration Certificate which is currently valid but expiring on or after 15.12.2020 (i.e. after commencement of the Cosmetics Rules, 2020) be considered valid until 15.06.2021 as per Rule 72 'Savings'?

Ans. As per rule 72 (i), the approvals or licences or permissions or certificate, issued under the provisions of the Act and the Drugs and Cosmetics Rules, 1945 in respect of cosmetics prior to commencement of these rules, shall be deemed to be valid for all purposes still its expiry or for a period of eighteen months from the date these rules are notified, whichever is later, under the corresponding provisions of these rules.

Q.73 Whether my old Registration Certificate (Form 43) granted under the Drugs and Cosmetics Rules, 1945 will remain valid in perpetuity under the Cosmetics Rules, 2020?

Ans. No. The Registration Certificate granted in Form COS-2 under the Cosmetics Rules, 2020 shall remain valid in perpetuity subject to the payment of registration certificate retention fee.

Q.74 Can someone apply for import of cosmetic in Form COS-4A if that cosmetic product is already registered under old registration certificate (i.e. Form 43) but not in Form COS-2 of the Cosmetics Rules, 2020 for import into India?

Ans. No. A cosmetic manufactured at a foreign site and already registered under Rule13 (Form COS-2) for import and sale in India, may be imported by any person or entity by making an online application in Form COS-4 for grant of Import Registration Number in Form COS-4A in SUGAM with an undertaking as specified in Sixth Schedule.

Q.75 Does CDSCO grant neutral code to cosmetics manufactured for export?

Ans: No, as specified in proviso of rule 34(10) of the Cosmetics Rules, 2020, that where a cosmetic is required by the consignee to be not labelled with the name and address of the manufacturer, the labels on packages or containers shall bear a code number as approved by the State Licensing Authority.

Q.76 Can someone import cosmetics into India if the date of expiry/use before/use by date mentioned on its label/wrapper is less than six month from the date of import?

Ans: No. As per rule 18(2) of the Cosmetics Rules, 2020, “No cosmetics shall be imported unless the “Use Before or use by” date shown on the label, wrapper or container of the cosmetic is later than six months from the date of import”.

Q.77 Is there any changes in checklist for application for import registration of cosmetics in SUGAM portal?

Ans. No. There is no change in checklist for application for import registration of cosmetics on SUGAM. However, the forms/legal documents have been modified as per the Cosmetics Rules, 2020.

Q.78 I am importing a unit pack (Kit, Palettes etc.) containing different colors, shades, flavours, fragrances etc. and which is sold as a single unit pack in retail. Whether it will be a single variant or not?

Ans. Yes. If a unit pack (Kit, Palettes etc.) containing different colors, shades, flavours, fragrances or other inherent characteristics apart from the base formulation, which is sold as a single unit pack in retail, then it will be considered as a single variant.

Q.79 I am having a valid Registration Certificate (Form 43) issued prior to the implementation of the Cosmetics Rules, 2020. Can I apply for change of name or address in valid RC (Form 43)?

Ans: No. The firm need to apply for a fresh Registration Certificate under the Cosmetics Rules, 2020 with changed name or address of the firm.

Q.80 Whether the cosmetic to be imported into India need to be mandatorily tested before registration as per the Cosmetics Rules, 2020?

Ans: No. As per rule 20(3) of the Cosmetics Rules, 2020, “If the suspected contravention of the provisions of the Act or the rules is such as may have to be determined by test, the officer shall send the sample to the Laboratory established for the purpose for performing such tests

and the consignment of the said cosmetic shall be detained till such time, the test report on that sample is received from the Director of the said Laboratory or any other officer of the Laboratory empowered by him in this behalf”.

Q.81 Will the old cosmetics manufacturing licenses/approvals/permissions, which is currently valid but expiring on or after 15.12.2020 (i.e. after commencement of the Cosmetics Rules, 2020) be considered valid until 15.06.2021 as per Rule 72 ‘Savings’?

Ans. Yes. As per rule 72 (i), the approvals or licences or permissions or certificate, issued under the provisions of the Act and the Drugs and Cosmetics Rules, 1945 in respect of cosmetics prior to commencement of these rules, shall be deemed to be valid for all purposes still its expiry or for a period of eighteen months from the date these rules are notified, whichever is later, under the corresponding provisions of these rules.

Q.82 Whether the firm need to apply in new forms for grant license for manufacturing of cosmetics after commencement of the Cosmetics Rules, 2020 (i.e. after 15.12.2020)?

Ans. Yes. The firm shall make an application in Form COS-5 and Form COS-6 for grant of license and loan license, respectively for manufacturing cosmetics in India, to the concerned State Licensing Authorities under the Cosmetics Rules, 2020.

Q.83 What will be the validity of license/loan license granted in Form COS-8 and Form COS-9?

Ans. As per rule 30 of the Cosmetics Rules, 2020, a licence or loan licence issued in Form COS- 8 or Form COS- 9 shall remain valid in perpetuity, subject to payment of licence or loan licence retention fee as specified in the Third Schedule before completion of the period of five years from the date of its issue, unless, it is suspended or cancelled by the state Licensing Authority.

Q.84 Is prior permission required for manufacture of New Cosmetics in India?

Ans. Yes. Prior permission from the Central Licensing Authority i.e. the Drugs Controller General (I) is required for manufacture of New Cosmetics in India.

Q.85 What is procedure for prior permission for manufacture of New Cosmetics in India?

Ans. The applicant who want to manufacture new cosmetics in India, need to obtain a prior permission in Form COS-3 from the Central Licensing Authority by making an application (in offline mode) in Form COS-12 along with requisite fee and documents as provided in Chapter V of the Cosmetics Rules, 2020.

Q.86 What are the labelling requirements that need to be complied for manufacture of cosmetics in India?

Ans. Label of cosmetics either manufactured in India or imported shall comply with the provisions specified in rule 34 of the Cosmetics Rules, 2020.

Q.87. What standards need to comply for cosmetic products manufactured in India?

Ans: No cosmetic shall be manufactured unless it complies with the standards prescribed under Ninth Schedule of the Cosmetics Rules, 2020 or any other standards of quality and safety, applicable to it, and other provisions under the Rules.

Q.88 Whether cosmetics can be tested on animal in country?

Ans. No. As per rule 39(7), no person shall use any animal for testing of cosmetics.

Q.89 What are the necessary documents required to be submitted for grant of manufacturing license or loan license for cosmetics?

Ans. An application in Form COS-5 or Form COS-6 along with information and undertaking as specified in Part-II of Second Schedule of the Cosmetics Rules, 2020 and requisite fee as specified in Third Schedule need to be submitted to the concerned State Licensing Authorities for grant of license or loan license for manufacturing cosmetics in India.

Q.90 Whether any notification, inspection, order or notice issued under the Drugs and Cosmetics Rules, 1945 shall be deemed valid under the Cosmetics Rules, 2020?

Ans. Yes. As per rule 72(2), any things done or any action taken or purported to have been done or taken, including any rule, notification, inspection, order or notice made or issued or any appointment or declaration made or any operation undertaken or any direction given or any proceedings taken or any penalty, punishment, forfeiture or fine imposed under the Drugs and Cosmetics Rules, 1945 shall, be deemed to have been done or taken under the corresponding provisions of these rules and shall always remain valid for all purposes.