

File No.: COS/21/000187

Central Drugs Standard Control Organisation (HQ)
Directorate General of Health Services
Ministry of Health and Family Welfare
(Cosmetics Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Dated: 16-Apr-2021

To,

M/s Oriflame India Pvt Ltd, Ground Floor, M-10 South
Extension, Part II New Delhi, Delhi (India) - 110049

Sub:- Registration Certificate in Form COS-2 (R.C. No. COS-395/14) under Drugs and Cosmetics Act 1940, and rules made thereunder, for the purpose of import of cosmetics manufactured by M/s. Oriflame Research and Development Limited, Bray Business Park, Kilruddery, Bray Co., Wicklow-Ireland - (Ireland) Telephone No.: 91-011-40409000 FAX: 91-011-41551465 E-Mail : sumeet.jaiswal@oriflame.com Reg.

Sir/Madam,

Registration Certificate in Form COS-2 under the Cosmetics Rules, 2020 is herewith forwarded for the import of Cosmetics into India. Subject to the following conditions:-

1. The Registration Certificate shall be produced by the Authorized Importer/Distributor/Agents as and when required by the Licensing Authority/Regulatory Authority.
2. Dispute, if any, in respect of the payment of fees and submission of Bharatkosh challan, shall be settled between the bank and applicant.
3. The Cosmetics will be required to be withdrawn from sale in the events of non compliance of Standards.
4. Each consignment of the Cosmetics to be imported by you shall be accompanied by a test analysis reports.
5. This Registration Certificate, unless it is sooner suspended or cancelled, shall be valid in perpetuity, subject to payment of Registration Certificate Retention Fee before completion of five years from the date of its issue.
6. No cosmetics shall be imported unless it complies with the specifications prescribed under Ninth Schedule and Tenth Schedule or any other standards of quality and safety, applicable to it, and other provisions under the rules. In case the cosmetics is not included under Ninth Schedule, it shall meet with specification under the rules and standards applicable to it in the country of origin.
7. The firm shall submit authenticated/ apostilled copy of documents viz. authorisation to this office, after normalization of the situation of COVID-19 or within 04 months, whichever is earlier.

Please note that Registration Certificate issued is liable to be suspended/ cancelled, if any of the conditions stipulated above is not complied with, apart from any other conditions that may be taken under the provision of the Drugs and Cosmetics Act, 1940 and the Rules thereunder.

Please acknowledge the receipt.

CENTRAL LICENSING AUTHORITY
Seal/Stamp

Copy To: All Zonal, Sub-Zonal and Port Offices of CDSCO.



GOVERNMENT OF INDIA
Central Drugs Standard Control Organisation
Ministry of Health & Family Welfare
FDA BHAWAN, KOTLA ROAD, NEW DELHI - 110 002 (INDIA)

Form COS-2

[See rule 13(1) and 13(4)]

REGISTRATION CERTIFICATE

Import registration certificate to be issued for import of cosmetics into India

Registration Certificate No. COS-395/14

Date:16-Apr-2021

1.M/s. Oriflame Research and Development Limited , Bray Business Park, Kilruddery, Bray Co., Wicklow-Ireland - (Ireland)
Telephone No.: 91-011-40409000 FAX: 91-011-41551465 E-Mail : sumeet.jaiswal@oriflame.com having factory premises at
(List enclosed as Annex-I) has been registered under rule 13 as a manufacturer and is hereby issued this Registration Certificate.

2. Name(s) of cosmetics, along with their brand names and pack sizes and variants which may be imported under this
Registration Certificate:

List enclosed as Annex-I

3. This Registration Certificate shall be in force from 15-Apr-2021 valid upto 14-Apr-2026 unless it is sooner suspended or
cancelled under the rules.

4. This Registration Certificate is issued through the office of the manufacturer or his authorised agent or importer in India or by
the subsidiary in India authorised by the manufacturer, namely M/s Oriflame India Pvt Ltd, Ground Floor, M-10 South
Extension, Part II New Delhi, Delhi (India) - 110049 who shall be responsible for the business activities of the manufacturer, in
India in all respects.

5. This Registration Certificate is subject to the conditions, stated below and to such other conditions as may be specified in the
Drugs and Cosmetics Act, 1940 and the rules made thereunder, from time to time in this regard.



Conditions of the Registration Certificate

1. The registration certificate shall be produced by the authorised importer or distributor or agent as and when required by the Licensing Authority or regulatory authority.
2. The manufacturer or his authorised importer/distributor/agent in India shall inform the Licensing Authority forthwith in the event of any administrative action taken namely, market withdrawal, regulatory restrictions, or cancellation of authorisation, and not of standard quality report of any cosmetic pertaining to this registration certificate declared by the Regulatory Authority of the country of origin or by any Regulatory Authority of any other country, where the cosmetic is marketed/sold or distributed.

The dispatch and marketing of the cosmetic in such cases shall be stopped and the Licensing Authority shall be informed immediately. Further action in respect of such stopped marketing of cosmetic shall be followed as per the direction of the Licensing Authority. In such cases, action equivalent to that taken with reference to the concerned cosmetic in the country of origin or in the country of marketing shall be followed in India also, in consultation with the Licensing Authority. The Licensing Authority may, however, direct any further modification to this course of action, including the withdrawal of the cosmetic from Indian market within 48 hours time period.
3. The manufacturer or his authorised agent or importer or distributor or subsidiary in India shall inform the Licensing Authority within thirty days, in writing, in the event of change in labelling or composition or testing, or specification or in documentation of any of the cosmetic pertaining to this Registration Certificate along with an undertaking that the products comply with standards laid down by the Bureau of Indian Standards as referred in the Ninth Schedule.
4. The manufacturer or his authorised agent in India shall inform the Licensing Authority immediately in writing, in the event, of any change in the constitution of the firm operating under this registration certificate. Where any such change in the constitution of the firm takes place, the current Registration Certificate shall be deemed to be valid for a maximum period of one hundred and eighty days from the date on which the change has taken place unless, in the meantime, a fresh registration certificate has been taken from the Licensing Authority in the name of the firm with the changed constitution of the firm.
5. In case of change in name or address of a registration holder or overseas manufacturer, operating under this registration certificate, an application for amendment shall be made in online portal of Central Government for prior approval from the Central Licensing Authority for the said changes in registration certificate within a period of sixty days from the date of such change.
6. The importer shall notify to the Licensing Authority immediately in writing, on the class of the cosmetic product which present a risk to the human health and the corrective measure taken.