

## A REVIEW ON REGULATORY CRITERIA FOR COSMETIC APPROVAL IN BRAZIL AND INDIA

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### ABSTRACT

This review delves into the regulatory standards for the approval of cosmetics in Brazil and India, elucidating the respective frameworks in place. In Brazil, the categorization of cosmetics is outlined in RDC No. 7, which is under the supervision of the National Health Surveillance Agency (ANVISA) and GHCOS, featuring a comprehensive set of regulations that encompass aspects such as product registration, labelling, and ingredients. The classification of products into Grade 1 and Grade 2 is determined by risk level, each with specific requirements for registration and dossier submission. The cosmetics industry in India, governed by the Drugs and Cosmetics Act, is monitored by the CDSCO. Regulatory measures in India mandate meticulous labelling, safety disclosures, and a well-defined process for import registration. A comparative examination demonstrates resemblances in the classification system and prohibited components, while also underscoring discrepancies in terms of documentation, fee schedules, and import protocols. Both nations stress the importance of rigorous adherence to regulations to safeguard consumer well-being and uphold the integrity of the market.

**Key Words:** Cosmetics, Labelling, Regulatory regulations, Import, comparative study

### 1. INTRODUCTION

In Brazil, Perfumes, cosmetics, and personal care products are defined in Brazil as mixtures of natural and synthetic ingredients intended for external application on various body parts, including the skin, hair, nails, lips, teeth, and mucous membranes of the mouth. The primary purposes of these products include cleansing, imparting scent, enhancing their aesthetic appeal, addressing body odors, and preserving or enhancing their optimal condition. (1,2,3)

In India, "Cosmetic products encompass a wide array of items, including creams, perfumes, lotions, skin cleansing agents, and products within the realm of decorative cosmetics. The term cosmetic originates from the Greek term "kosmtikos," denoting "capable of organizing and adorning." (4,5,6)

In India, the cosmetics industry is experiencing a growth rate of approximately 20% annually; however, the regulatory standards in India are intricate and time-intensive, necessitating approvals both before and after market release. Cosmetic products in India are classified into various categories such as skincare, haircare, oral care, color cosmetics, fragrances, and other categories. With a current valuation of USD 6.5 billion, the Indian cosmetic market is forecasted to reach USD 20 billion, demonstrating a compounded annual growth rate of 25% by 2025. Moreover, the global cosmetics market is anticipated to reach USD 450 billion, with a compounded annual growth rate of 4.3% by the year 2025. (7,8)

### 2. BRAZIL'S COSMETIC REGULATORY AUTHORITIES: (3)

ANVISA: promotes the protection of public health by controlling the production and consumption of products and services that are subject to sanitary surveillance, such cosmetics.

GHCOS: Coordinates, oversees, and manages the registration, information gathering, inspection, formulation of norms and standards, and adherence to rules pertaining to the hygienic surveillance of personal hygiene products, cosmetics, fragrances, and sanitizers.

#### 2.1 The Cosmetic Regulations in Brazil:

**Table 1:** Brazil Cosmetic Regulations

Subject	Rules
Enrolments	<p>Technical requirements for the regularization of cosmetics, fragrances, and personal care items are included in RDC 07/2015.</p> <ul style="list-style-type: none"> <li>RDC 15/2015 contains the technical specifications needed for the regularization of children's cosmetics, fragrances, and personal care items.</li> </ul> <p>The registration requirements for cosmetic goods that repel insects are outlined in RDC 19/2013.</p> <ul style="list-style-type: none"> <li>RDC 237/2018 implements changes to several of the provisions of RDC 07/2015 and RDC 15/2015.</li> </ul>

Labelling	<ul style="list-style-type: none"> <li>Annex V, Annex VI, and Chapter II are stated in RDC 07/2015.RDC 250/2018: Multiple art of labeling options or labels for the same product are allowed under this set of guidelines for the presentation of the Art of Labelling Project during the regularization process of perfumes, cosmetics, and personal care goods.</li> </ul>
Ingredients	<ul style="list-style-type: none"> <li>The F List of PRT 344/1998 is updated with substances prohibited in Brazil.</li> <li>RDC 83/2016: A list of ingredients that are not allowed to be used in makeup, toiletries, or fragrances is given.</li> <li>RDC 3/2012: A list is outlined of substances that should not be included in toiletries, cosmetics, and perfumes, except under specified conditions and restrictions.</li> <li>RDC 29/2012: List of permitted preservative-acting substances for toiletries, cosmetics and perfumes</li> <li>RDC 44/2012: List of permitted colouring substances for toiletries, cosmetics and perfumes</li> <li>RDC 69/2016: List of allowed ultraviolet filters for toiletries, cosmetics and perfumes</li> </ul>

## 2.2 Classification: (2,9,10)

In Brazil, cosmetics are categorized into two classes based on the presence of adverse effects or risks arising from the use of the product, its composition, and the application site.

**Class 1:** encompasses products with basic characteristics that do not necessitate extensive labelling. This category includes items such as mouth fresheners, facial/body foundations, lipsticks, blush (excluding sunscreens), conditioners, creams, lotions, toothpastes, epilators, nail polish, kajal, other eye cosmetics, bath products, pre-shaving and shaving products, and shampoos.

**Class 2:** These products are required to have specific indications, demonstrate safety and efficacy, and include details on their mode of action and restricted usage.

Examples of Class 2 products are childcare items, sunscreens in lotion form, hair straightening products, and antiseptic soaps.

## 2.3 Process of Registration:(3)

### Grade 1:

- The products in question are duly notified in compliance with the rules outlined in RDC 343/2005.
- For Grade I products, it is imperative to provide notification through "prior communication" via the cosmetic Automation System (SGAS).
- Subsequently, upon completion, Once the product is approved for commercialization, it usually takes two months for the website to publish the notification.

**Step 1:** The company registers with the SGAS.

**Step 2:** involves registering the product to be shared in the SGAS.

**Step 3:** You will be required to pay the Health Surveillance Inspection Fee (TFVS).

**Step 4:** No physical documents delivery is necessary; the protocol process is completed online.

Following the TFVS payment's confirmation, the online protocol is automatically generated in the SGAS.

➤ The electronic approach must result in papers that need to be printed and signed by both the Legal Representative and the Technical Responsible party.

➤ These records have to be kept on file at the business and made accessible for hygienic surveillance activities.

**Step 5:** Utilising the SGAS to monitor the request for prior communication.

**Step 6:** After advertising on ANVISA's website, the product may be commercialised.

The company will become authorised to market the product after it has petitioned the product in SGAS and paid TFVS, and the status "Exempt from Registration" will be displayed.

### Grade 2:

➤ These particular products are subject to registration under the provisions of RDC 211/2005.

➤ This complete procedure could extend for a duration of up to 90 days. Furthermore, the registration remains valid for a period of five years, necessitating the renewal of the documentation during the first half of the fifth year. The registration fee is contingent upon the size of the company, ranging from R\$244.05 to R\$4.88100 Brazilian reais.

**Step 1 - Company Health Regularization:** The process of regularizing the health status of the company involves acquiring the Company Operating Authorization (AFE), obtaining local health licenses, and ensuring adherence to Good Manufacturing Practices.

**Step 2 - Identification of the petition at ANVISA:** This stage requires the identification of the specific subject code associated with the petition and the verification of the necessary documentation on the official ANVISA website.

**Step 3 - Petition at ANVISA:** The commencement of the petition procedure takes place on the ANVISA website, leading to the issuance of the Health Surveillance Inspection Fee (TFVS). Subsequently, after the payment of the fee, it is crucial to furnish the obligatory documentation and formally register the petition via the ANVISA website.

**Step 4 - Analysis of the petition by ANVISA**

**Step 5 - Result of the petition:** The evaluation of the petition is conducted by ANVISA, and the outcome, whether approval or rejection, is subsequently published in the Official Gazette (DOU).

**2.4 Dossier: (11)**

For both Grade 1 and Grade 2 items, a dossier is required. In-depth details about the components utilized, their amounts, label claims, stability data, results from quality control tests, and microbiological should all be included. Further proof of safety and effectiveness is required for Grade 2 products.

The following is included in the dossier that was filed for Grade 1 items that are going through the notification process:

- Sheet of Product Composition (PCS).
- The purposes of the components and the required technical citations.
- Product specifications, including final product physical, chemical, and organoleptic properties.
- Microbiological attributes.
- Packaging specifications.
- Results of stability tests.
- Original language and Portuguese versions of the label artwork.
- Description of the final product.
- In the case of imported products, a Free Sale Certificate from the originating country is required.

The subsequent dossier has been presented for Grade 2 items that are subjected to the Registration procedure:

- Product composition sheet (PCS).
- Functions and necessary technical references of ingredients.
- Product specifications including physical, chemical, and organoleptic characteristics of the end product. Microbiological traits.
- Packaging requisites.
- Evaluation of product stability.
- Original language and Portuguese labeling artwork.
- Description of the final product.
- In the case of imported products, submission of a Certificate of Free Sale issued by the originating country is mandatory.
- Presentation of results supporting product claims.
- Safety data pertaining to the product.

**2.5 Labelling: (2,12)**

The regulations such as RDC07/2015 and RDC 250/2018 address the requirements concerning the labeling of cosmetic products. These requirements encompass general stipulations. It is essential for the label of both categories to contain the company's license authority number (AFE).

**Table 2: Labelling**

Primary	Secondary	Primary and Secondary
Lot or batch number	Product registration number	Product and group name
	Expiration date	Brand
	Net content	Instruction on how to use product

	Country of origin	Warnings of use and product risks
	Manufacturer/importer/regularization holder and address	Specific label
	Product chemical formula	

### 2.6 Special Labelling: (2,13)

- For aerosols, it is important to note that they are flammable. It is advised not to spray them near an open fire. Additionally, they should not be punctured or incinerated, nor should they be exposed to direct sunlight. It is recommended to protect the eyes when applying aerosols and to keep them out of reach of children.
- When using neutralizing products for curling and smoothing the hair, users should avoid application if any irritation or injury occurs. These products should also be stored away from children.
- Agents found in hair lighteners and hair dyes possess the capability to induce allergic responses. It is not recommended to apply these substances on eyelashes or eyebrows. Similar to various hair care products, if any form of irritation or harm is observed, the application should be discontinued, and these products must be kept out of reach of children.
- Products such as depilatories and epilators should be avoided if irritation or harm is experienced, and they should not be used for shaving purposes. Furthermore, these items should be stored away from children.
- Fluoride toothpaste and mouthwashes ought to prominently show the fluoride concentration in parts per million. Using these products on children younger than six is not advised.
- Antiperspirant products should only be used in the designated area as specified on the packaging.
- In the case of hair tonics, if irritation occurs, it is advised to discontinue use promptly.

### 2.7 Authorization of Cosmetics in Marketing: (10,14)

Marketing authorization of cosmetics in Brazil encompasses two distinct types: registration and prior notification.

#### Procedure for Grade 1 items (prior notification products):

**Step 1:** Registration of the company constitutes the initial phase required to obtain authorization for the petition system, facilitating the registration of private entities and establishing a formal bond between the user and the organization.

**Step 2:** Modification of the company's scale (if desired) entails a fee structure that is contingent upon the company's size, with ANVISA often categorizing a significant proportion of entities as large corporations.

**Step 3:** Submission of the formal request was executed within the SGAS platform.

**Step 4:** The issuance of a payment document occurred upon completion of the petition, with the fee being stipulated by the Interministerial Ordinance. Tracking the progress of the procedure is achievable through SGAS, with the validity period extending up to 5 years.

#### Procedure for registering pharmaceuticals (Grade 2 items):

The petition system is used to submit the registration request.

**Step 1:** Registration of a Company is the initial procedure required to obtain authorization for accessing the petition system. This stage is particularly relevant to the enrollment of privately owned enterprises. and establishing a formal bond amongst the client and business.

**Step 2:** Modification of the company's scale (if applicable) incurs a fee is subject to variation based on the scale of the organization, as defined by ANVISA, which often categorizes a significant portion of companies as large entities.

**Step 3:** Submission of a Request involves the party first identifying the relevant subject code and subsequently initiating the request process.

**Step 4:** Payment is facilitated through the issuance of a payment document upon completion of the petition. The fee is determined based on the regulations specified in the Interministerial Ordinance.

**Step 5:** Protocol for Document Submission necessitates the party to compile all required documents as outlined in the provided checklist. The eligibility of products is publicly announced in the Brazilian Official Journal and remains valid for a period of five years.

### 2.8 Cosmetics Import: (15,16)

Procedure that must be adhered to by any organization aiming to import a commodity into Brazil entails the submission of a registration application to the relevant governing body, accompanied by the requisite documentation endorsed by both the technical head and the legal delegate. In cases where qualitative and quantitative data are lacking, a certificate

of unrestricted commerce from the nation of origin, sanctioned by the Brazilian consulate in that jurisdiction, is mandatory. Additionally, evidence of payment for the stipulated charges is obligatory. The firms necessitate details concerning the safety of the merchandise. Subsequently, the paperwork should encompass the appropriate labels, with the likelihood of utilizing photocopies if the original label contains the essential particulars. Furthermore, it is essential to explicitly state that components comply with the national regulations pertaining to public health. Requesting authority may take up to 60 days.

### 3. COSMETIC REGULATION IN INDIA

The Drug and Cosmetics Act 1940 and the restrictions that followed, which went into effect in 1945, govern the regulation and management of cosmetics in India. The Central Drug Standards Control Organization (CDSCO) is the governing body responsible for overseeing cosmetics laws in India. It operates under the command of the Drugs Controller General of India. Furthermore, the primary national standards body in India is the Indian Standards Bureau (BIS), the principal national Standards Body in India is known as the Bureau of Indian Standards, is charged with creating standards and recommendations for the labelling of cosmetic products, which are listed in Cosmetics and Drugs Act, Schedule 'S'. (17,18,19,20)

Manufacturers are required to get a cosmetic license in compliance with the guidelines specified in the 1940 Cosmetics and Drugs Act. This license, permitting the manufacture of cosmetics for sale or distribution, is granted through the utilization of Form No. 32. The procedure for applying includes submitting Form No. 31, accompanied by a fee of Rs. 2500 and an inspection fee of Rs. 1000 in case none of the items within a category surpass ten. (21)

The documents appended to the application include: (22,23)

- A blueprint illustrating the layout of the factory premises
- An inventory detailing all equipment and apparatus intended for installation
- A written account outlining the organizational framework of the enterprise.
- Official records attesting to the applicant's ownership of the proposed manufacturing premises, such as a lease receipt.
- Form no. 32A is specifically utilized to request a loan license for the production and distribution of cosmetic products, while form no. 31A is employed to submit the application.
- Form no. 37 is designated for the procurement or renewal of a permit required for the manufacturing and retailing of pharmaceuticals and cosmetics.

#### 3.1 Indian Regulations for the Labelling of Imported Cosmetics:

Labels for all packaged goods must include the following information: (24)

- The importer's name and contact details
- The product's generic or widely used name that is being package
- The net quantity shown in weight and measurement standards
- The packaging's month and year showing the product's manufacturing, packing, or importation date
- The packaged product's maximum retail sales price (MRP), which is the amount the final consumer will pay for it.

**MRP:** (24)

The MRP consists of the following:

- taxes,
- goods transport fees,
- dealer commission, and all expenses related to advertising,
- delivery, packaging, and forwarding.

Both the interior and exterior labelling of cosmetic items must clearly convey the following specific information:

- The brand name of the makeup.
- The components listed in the order of percentage of content are the name of the producer and the full address of the production facility where the cosmetic was created.

#### For the label on the outside:

- A statement outlining the precise quantity of contents in liquid measurements and weight for solids and semi-solids.
- components arranged based on the percentage of each in the finished product.

#### On the internal label:

- terminology that highlights any possible dangers.



- appropriate directions for the product's safe usage, such as a warning, a caution, or a thorough instruction that the user must adhere to
- The identification and levels of any substances that could pose a danger or risk of fatality must be explicitly stated.
- The components are presented according to their percentage of the total composition, decreasing.
- Batch codes commencing with the letter "B."
- Soap labels should feature the month and year of production instead of using a batch code.
- A figure preceded by the letter "M" signifies a manufacturing permit.

### **3.2 Import Registration Process: (25)**

central drug standard control organization (CDSCO) must receive an application as a kind of FORM 42 together with a cover letter as the first step in the enrolment procedure for the importation of cosmetics.

Consequently, it is expected that the registration certificate will be obtained within a timeframe of 6 months from the date of submitting the application. Subsequent to this, the registration's validity is extended for a period of 3 years, following which a renewal procedure is imperative to guarantee the uninterrupted flow of import activities.

### **3.3 Providing the following documents is required for the registration process:**

- A valid Import Export code (IEC) is essential.
- It is required to provide verification or evidence of payment for the registration fees.
- Detailed particulars regarding the manufacturer and the corresponding manufacturing facility are required.
- Comprehensive information pertaining to the cosmetic product such as its brand title, quantity, and date of production is necessary.
- It is crucial to provide a detailed explanation of the nations from where the goods is supposed to be imported.
- Complete enumeration of the constituents and ingredients utilizing both the international nomenclature and the specific amount of each ingredient is imperative.
- Submission of the label sample document inclusive of its specifications is a prerequisite.

### **3.4 Time period required for the issuance of an import license: (26)**

The Competent Licencing Authority (CLA) will grant an import licence using Form 10 if the application is appropriately submitted. Three months are typically needed for this process to complete after the application is approved.

### **3.5 Instructions for completing the Form 43 registration certification application to have the capability of importing cosmetic products. (26,27)**

- Cover letter
- Attorney power of attorney
- Scheduling D III
- Compendium of ingredients
- The product labels that are being suggested
- Standardisation
- Package additions
- Licences for manufacturing
- Complimentary vouchers of sale
- Declaration of non-animal testing
- Heavy metal and hexachlorophene content declaration

### **Additional records: (28)**

- Application form Number 42
- Cost (online Bharatkosh payment)

### **3.6 Rules on Misbranded and spurious cosmetics: (24,29)**

#### **For Misbranded Cosmetics:**

The following situations qualify a cosmetic product as misbranded under the D&C regulations:

- Inclusion of any dye, color, or pigment that is not recommended.
- Failure to adhere to proper labeling guidelines.
- the label or box contains false or misleading information.

#### **For Spurious Cosmetics:**

As stated by the D&C statute, a cosmetic product is deemed spurious if:

- Under a name that sounds similar to another cosmetic product, it is imported.
- It imitates, replaces, or shares a similar name with an existing cosmetic item.
- The label or packaging falsely attributes the product to an individual or company that did not manufacture it.
- It gives the false impression of being connected to a specific company or manufacturer.

**4. Comparison of cosmetic regulatory requirements between Brazil and India: (1,30,31)**

**Table 3:** Comparison of regulations in Brazil and India

Country/contents	Brazil	India
Authority/Governing body	ANVISA	CDSO
What constitutes a cosmetic	In Brazil, anything intended for application is considered a personal care product, cosmetic, or scent, rubbed, poured, sprinkled, sprayed, or items that contain natural or synthetic elements intended for external application on several bodily parts of humans, including the lips, skin, hair, nails, genitalia, teeth, and oral mucosa. Their primary objectives are to deodorize, clean, smell good, enhance beauty, and maintain or preserve various body components.	Anything that is meant to be poured, rubbed, cleaned, polished, made more appealing, sprayed, rubbed, sprinkled, sprayed, or introduced into the anatomy of humans in any other way; this includes anything that's intended to be a component of makeup.
Rules and Regulations/Legislation	RDC regulations	Act on Drugs and Cosmetics
Date of Expiration	Not stated	With a "Use Before Date" indication
Expiry date labelling	Best before the date	Expiration date
Label language	Portuguese	English
Company registration	Required through Petition System	Required Under state Government Licensing
Classification	Grade I and Grade II	various categories, such as hair and skin care
Fee Structure	Varies by Company Size	Rs. 2500 for application, Rs.1000 for Inspection
Document Submission	Extensive Documentation Including Labels and safety Info	Detailed documents Including layout, equipment etc.
Import Procedure	Detailed, includes Certificate of free trade	Detailed, requires registration under rule 129D
Labelling requirements	Detailed labels including safety instructions	Detailed labels including ingredient percentages
Product safety	Compliance with national health regulations	Testing for heavy metals and other specifications
Marketing duration	Valid for 5years	Not specified
License renewal	Not specified	Form No. 37 for renewal
Prohibited Substances	Lists Specific Prohibited substances	Lists Specific Prohibited substances including hexachlorophene
Inspection and licensing	Through State and Central authorities	Through State Licensing Authorities
Non-Compliance Penalties	Not Specified	Adulterated, misbranded, and Spurious Cosmetics Regulations

Importing Regulations	Registration process, ANVISA approval	Compulsory registration, Ministry of Health Approval
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#### 4. CONCLUSION

Brazil and India have regulatory requirements for cosmetic approval to safeguard the safety and quality of cosmetic products for consumers. However, Brazil's regulatory agency, ANVISA, is considered to be more stringent compared to India's regulatory bodies. While complying with ANVISA's regulations can be a complex process, it opens doors to the Brazilian market for manufacturers and importers. India's regulations aim to ensure the safety, quality, and efficacy of cosmetic products through safe ingredients and proper labeling. In essence, both countries prioritize consumer safety but with varying levels of strictness.

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