

Cosmetics – Regulatory

Definition of Cosmetic Products (As per Indian Regulation)

- Under the **Drugs and Cosmetics Act, 1940**, a cosmetic is any substance intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering appearance without affecting body functions or structure.

Legal definition (simplified)

- A cosmetic includes** any article intended to be **rubbed, poured, sprinkled, sprayed, or applied to:**
 - Skin
 - Hair
 - Nails
 - Lips
 - Teeth

Purpose of cosmetics

- Cleaning (e.g., soaps, shampoos)
- Beautifying (e.g., creams, powders, lipsticks)
- Altering appearance (e.g., hair dyes, perfumes)
- Maintaining hygiene (e.g., deodorants, toothpaste)

Important clarification

- Cosmetics do NOT treat or cure diseases
- If a product claims to treat skin conditions, it may be classified as a **drug**, not a cosmetic

Examples of cosmetics

- Face cream, lotion
- Shampoo, conditioner
- Lipstick, nail polish
- Perfume, deodorant
- Toothpaste (only for cleaning, not medicated ones)

Key distinction

- **Cosmetic:** External use, aesthetic purpose
- **Drug:** Therapeutic or medicinal purpose

Borderline cases

- Anti-dandruff shampoo → may be both cosmetic and drug
- Sunscreens → sometimes regulated as drugs due to protective function

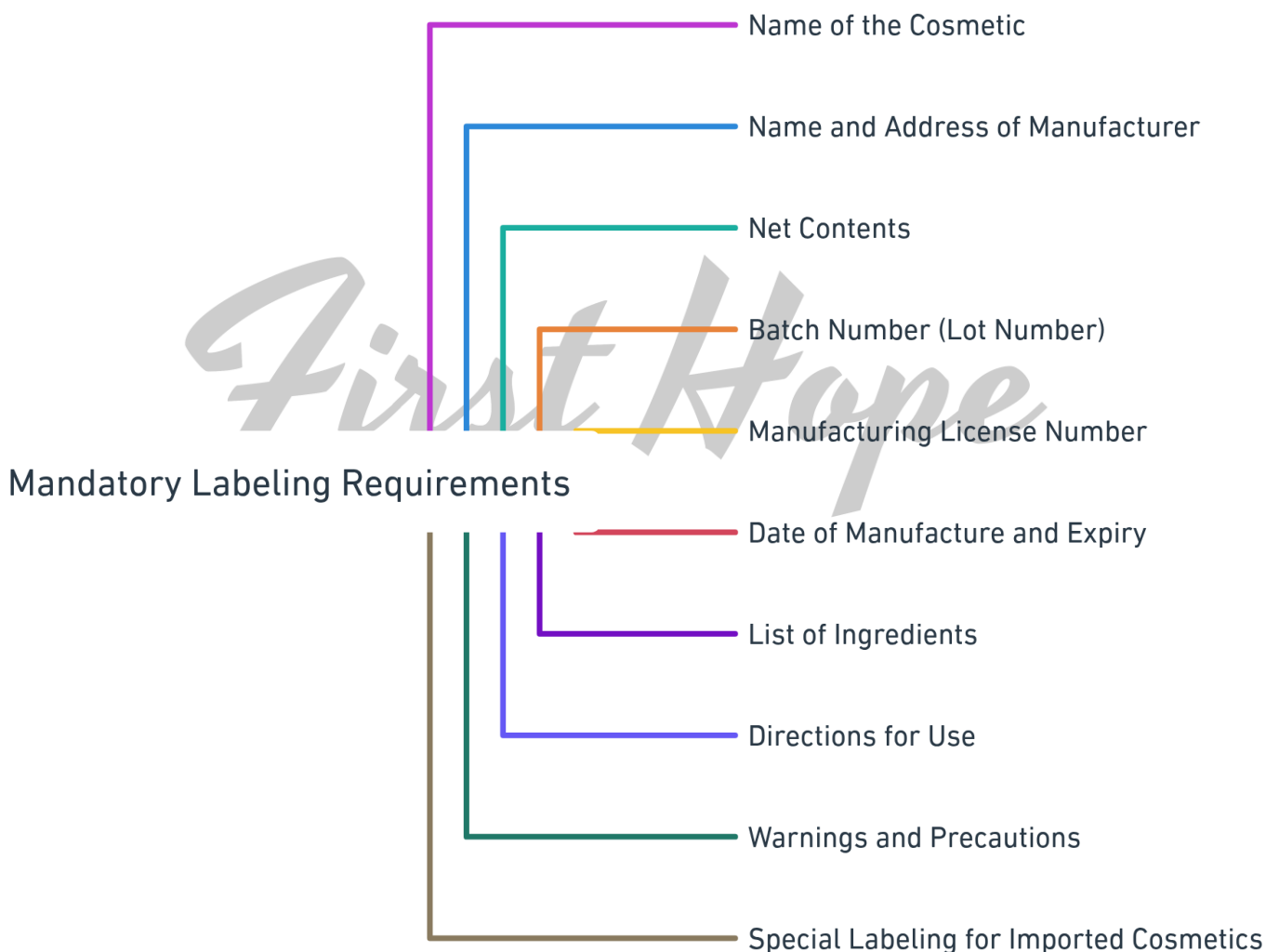
Indian Regulatory Requirements for Labeling of Cosmetics

- Labeling ensures that consumers receive **complete, clear, and truthful information** about the cosmetic product.

Legal authority

- Governed by **Drugs and Cosmetics Rules, 1945**

Mandatory labeling requirements



A. Name of the cosmetic

- Must clearly state what the product is (e.g., "Moisturizing Cream")

B. Name and address of manufacturer

- Full address of manufacturing site
- If manufactured by a third party, details must still be provided

C. Net contents

➤ **Quantity must be mentioned:**

- Weight (g)
- Volume (ml)

D. Batch number (Lot number)

- Helps in tracking manufacturing details
- Important for recalls and quality control

E. Manufacturing license number

- Indicates approval by regulatory authority

F. Date of manufacture and expiry (or "Best before")

- Ensures product safety and effectiveness

G. List of ingredients

- **Required especially if product contains:**
 - Hazardous substances
 - Allergens
- Ingredients usually listed in descending order of quantity

H. Directions for use

- Clear instructions for safe and proper use

I. Warnings and precautions

- **Example:**
 - "For external use only"
 - "Avoid contact with eyes"

J. Special labeling for imported cosmetics

- **Must include:**
 - Importer's name and address
 - Registration certificate number

Special labeling rules

- Imported cosmetics must mention **importer details**
- Certain colors and preservatives must be declared

Prohibited labeling practices

- False or misleading claims
- Claims of curing diseases

- Imitating another product's identity

Regulatory Provisions Relating to Import of Cosmetics

Basic Idea

- Import of cosmetics into India is strictly regulated to ensure **safety, quality, and compliance** with standards.
- Products must meet **Indian regulatory requirements** before being marketed.

Regulatory Authority

- Central Drugs Standard Control Organization (**CDSCO**)

Registration Requirement

- Every cosmetic imported into India must be registered.
- Imports without registration is illegal.

Registration Certificate

- Application submitted in Form COS-1
- Certificate issued in Form COS-2
- **Validity:** Usually 3 years

Who Can Apply

- Manufacturer
- Authorized agent in India
- Subsidiary of manufacturer

Documents / Key Requirements

- Manufacturer details
- Product details and specifications
- Ingredient list
- Manufacturing process
- Safety data
- Label samples (as per Indian rules)
- Free Sale Certificate
- Confirms product is legally sold in country of origin

Conditions for Import

- **Product must:**
 - Meet Indian safety standards
 - Not contain banned or harmful substances
 - Be properly labeled as per Indian regulations
 - Be proven safe for use

Testing and Inspection

- Cosmetics may be inspected at ports of entry
- Samples can be tested in laboratories
- **Non-compliant products may be:**
 - Rejected
 - Destroyed

Distribution Consideration

- Each **variant or category** may require **separate registration**

Prohibited Imports

- **Cosmetics are not allowed if they:**
 - Contain harmful or banned ingredients
 - Are misbranded or spurious
 - Do not meet Indian standards

Post-Import Responsibilities

- Maintain proper records
- Report adverse effects
- Ensure consistent product quality

Misbranded Cosmetics

Basic Idea

- A cosmetic is **misbranded** if its labeling, packaging, or presentation is **false, misleading, or incomplete**.

Conditions for Misbranding

1. False or Misleading Label

- Claims that are not true
- Exaggerated or unproven benefits (e.g., "permanently removes wrinkles")

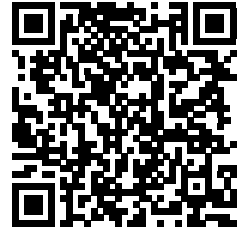


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