

Cosmetics Requirements

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Requirements for Imported Cosmetic Products in Venezuela

Below is the complete overview of regulatory requirements in Venezuela for the sanitary registration of imported cosmetic products, including prerequisites, dossier documentation, labeling requirements, and estimated approval timelines.

The responsible authorities are the Ministry of People's Power for Health (MPPS) and the Autonomous Health Comptroller Service (SACS).

Sanitary Registration of Imported Cosmetics in Venezuela

1. Applicant Prerequisites

Before applying for registration:

- Importing company legally established in Venezuela
- Valid sanitary operating license
- Establishment registered with SACS
- Designated sanitary responsible person
- Representation agreement with the foreign manufacturer
- Manufacturer authorization to commercialize the product in Venezuela

2. Administrative Documents

Administrative section of the dossier:

- Official sanitary registration application form
- Importer sanitary license
- Company commercial registration
- Apostilled Power of Attorney from manufacturer to Venezuelan representative

- Free Sale Certificate from country of origin
- Trademark authorization (if applicable)
- Proof of payment of regulatory fees
- Product holder declaration

3. Technical Requirements of the Dossier

3.1 Product Information

- Product trade name
- Type of cosmetic and presentation form
- Complete qualitative and quantitative formula (ingredients in INCI nomenclature)
- Function of each ingredient
- General manufacturing process description
- Physicochemical specifications
- Microbiological specifications
- Proposed shelf life and storage conditions
- Packaging type and materials

3.2 Product Safety

- Toxicological evaluation of ingredients
- Cosmetic product safety declaration
- Manufacturer certificates of analysis
- Compliance with permitted/restricted ingredient lists

3.3 Samples

- Commercial product samples when required by the authority

4. Cosmetic Labeling Requirements

Labeling must be in Spanish and submitted within the dossier for approval.

Mandatory label information:

- Product name
- Cosmetic function
- Ingredient list (INCI) in descending order
- Net content (g, mL)
- Manufacturer name and address
- Importer name and address in Venezuela
- Country of origin
- Batch number

- Expiration date or PAO symbol when applicable
- Storage conditions
- Warnings and precautions for use
- Sanitary registration number (once granted)

Labeling documents within the dossier:

- Final artwork of primary packaging
- Final artwork of secondary packaging
- Official Spanish translations when applicable
- Signed declaration of labeling compliance

5. Additional Requirements

- Apostilled or legalized foreign documents
- Official Spanish translations of technical documents
- Payment of regulatory fees
- Declaration of compliance with Venezuelan sanitary regulations

6. Estimated Approval Timeline

Timelines depend on cosmetic type and technical observations:

Typical timelines:

- Administrative review: 1 – 2 months
- Technical evaluation: 3 – 5 months
- Laboratory analysis (if required): 1 – 3 months

Average total time:

- 6 - 9 months under normal conditions.

7. Validity of the Sanitary Registration

- Typical validity: 5 years
- Renewal requires updated formula, certificates, and current labeling