

Year XXXVI - Number 3847

Lima, December 17, 2019

**SUMMARY  
GENERAL SECRETARIAT OF THE ANDEAN COMMUNITY**

P.

**RESOLUTION N ° 2120** Andean Technical Regulations on Specifications  
Microbiological Techniques for Cosmetic Products. .... one

**RESOLUTION N ° 2120  
Andean Technical Regulation on Microbiological Technical Specifications of  
Cosmetic products**

**THE GENERAL SECRETARIAT OF THE ANDEAN COMMUNITY;**

**HAVING SEEN:** Letter b) of Article 30 of the Cartagena Agreement, the First Final Provision of Decision 833, Decisions 615, 827 and 851, and Resolutions No. 1418, No. 1482 and No. 2108; and,

**WHEREAS:** Decision 827 establishes the guidelines for the preparation, adoption and application of technical regulations and evaluation procedures of the conformity in the Member Countries of the Andean Community and at the community level;

That, the First Final Provision of Decision 833, on Harmonization of Legislations Regarding Cosmetic Products, it establishes that the General Secretariat, with recommendation of the Competent National Authorities of the Member Countries, adopt by resolution, the provisions that regulate the correct application of the aforementioned Decision;

That, Resolution No. 1418 and its amendment, Resolution No. 1482, establish the microbiological content limits of cosmetic products;

That, Resolution No. 2108, in its article 8, establishes that, for the specifications required microbiological, as established in literal l) of article 9 of the Decision 833, cosmetic products that are marketed in the Andean Subregion must comply with the Andean Technical Regulations approved by the General Secretariat of the Andean Community through Resolution; and

That, the Group of Government Experts for the Harmonization of Legislations Sanitary (Human Health), in its meeting held on December 9, 2019, recommended to the General Secretariat of the Andean Community the adoption through Resolution of the Andean Technical Regulation on Technical Specifications Microbiological of Cosmetic Products.

**RESOLVES:**

Approve the Andean Technical Regulation on Technical Specifications Microbiological of Cosmetic Products contained in this Resolution, corresponding to the Member Countries their due application.

For us, the Homeland is America

**ANDEAN TECHNICAL REGULATION ON TECHNICAL SPECIFICATIONS  
MICROBIOLOGICS OF COSMETIC PRODUCTS**

**CHAPTER I  
OF THE PURPOSE, FIELD OF APPLICATION AND DEFINITIONS**

**Article 1.- Purpose.** The purpose of these Andean Technical Regulations is to establish the microbiological specifications that products must meet cosmetics that are marketed in the territories of the Member Countries, in order to protect human health or safety, as required in literal l) of article 9 of Decision 833 "Harmonization of Legislation in the field of cosmetic Products".

These Andean Technical Regulations also establish the specifications Physicochemical conditions of cosmetic products that are presumed to be free of microbiological contamination.

**Article 2.- Field of application.** These Andean Technical Regulations apply to cosmetic products identified in the indicative list of Decision 833, whose subheadings NANDINA are in Annex 1 of these regulations .

**Article 3.- Definitions.** For the purposes of these Andean Technical Regulations, The definitions established in Decision 833 and the regulations that the supplement or replace it.

**CHAPTER II  
OF MICROBIOLOGICAL TECHNICAL SPECIFICATIONS**

**Article 4.- Microbiological specifications.** The cosmetic products that marketed in the Andean Subregion must meet the microbiological specifications indicated in the following table, according to their area of application and age:

**Table No. 1  
Microbiological specifications**

APPLICATION AREA AND PHASE	LIMITS OF ACCEPTABILITY
<b>ETARIA</b>	
▪ Products for use in infants (up to 3 years)	to. Aerobic mesophilic microorganism count totals. Maximum limit $5 \times 10^2$ CFU / g or ml.
▪ Products for use in the area of eyes.	b. Absence of <i>Pseudomonas aeruginosa</i> in 1 g or ml.
▪ Products that enter contact with membranes mucous.	c. Absence of <i>Staphylococcus aureus</i> in 1 g or ml.
▪ Other cosmetic products susceptible to contamination microbiological.	d. Absence of <i>Escherichia coli</i> in 1 g or ml.
▪ Products to be used in external genital organs	to. Aerobic mesophilic microorganism count totals. Maximum limit $5 \times 10^3$ CFU / g or ml.
	b. Absence of <i>Pseudomonas aeruginosa</i> in 1 g or ml.
	c. Absence of <i>Staphylococcus aureus</i> in 1 g or ml.
	d. Absence of <i>Escherichia coli</i> in 1 g or ml.
	In addition to the specified acceptability limits for the other products contained herein box, must comply with: Absence of <i>Candida albicans</i> .

Note. The values of the sample size to be examined for the respective tests will be determined by the internal rules and procedures of the Member Countries.

**Article 5.- Physical-chemical conditions.** Cosmetic products that comply with any of the physical-chemical conditions established in the following table, They will presume that they are free of microbiological contamination:

**Table No. 2  
Physicochemical specifications**

CONDITION	LIMIT
acid pH	$\leq 3.0$

alkaline pH	≥ 10.0
Hydroalcoholic solutions	≥ 20%
Filling temperature	≥ 65.0 ° C
Water activity (aw)	≤ 0.75
Solvent-based products	Unlimited
Oxidizing products	Unlimited
Aluminum hydrochloride and related salts	15% to 25%

### CHAPTER III OF THE PROCEDURES FOR THE APPLICATION OF THE PRESENT ANDEAN TECHNICAL REGULATION

**Article 6.- Administrative procedure.** The application of this Regulation Andean Technician will be carried out according to the procedures for obtaining the Notification Sanitary Obligatory (NSO) of cosmetic products, their modification, renovation and recognition, established in Decision 833 and the Andean regulations that the supplement or replace it.

**Article 7.- Conformity Assessment Procedure (PEC).** In the app of this Andean Technical Regulation does not require a procedure conformity assessment to obtain the NSO required in article 6 of this Regulation. Notwithstanding this, the NSO Holder must maintain the certificates Analytical and test methods demonstrating compliance with specifications microbiological (Table N ° 1) or physicochemical (Table N ° 2) of this Regulation Andean Technician, as indicated in article 9 regarding control actions and health surveillance.

### CHAPTER IV CONTROL AND SURVEILLANCE

**Article 8.- Inspection and / or supervision authority.** The National Authority Competent of each Member Country, in exercise of the control and surveillance functions in the market, will be in charge of supervising compliance with the established in these Andean Technical Regulations.

**Article 9.- Inspection and / or supervision.** The Competent National Authority of each Member Country will carry out the supervision and control actions of compliance with this Andean Technical Regulations, as established in Chapter VII "Surveillance Sanitary" of Decision 833 and its amendments or the regulations that replace it.

In exercise of the functions of sanitary control and surveillance, the National Authority Competent may require the Head of the NSO, when they consider it, the presentation of the respective analytical certificate and the test methods necessary to demonstrate the compliance with the microbiological or physicochemical specifications established in these Andean Technical Regulations. Such methods must be standards-based

international, regional, national or of associations recognized internationally, as long as they are in force.

When the NSO Holder does not have the test method that demonstrates the compliance with the technical information of the cosmetic product required herein Andean Technical Regulations, the Competent National Authority may carry out or subcontract the respective analyzes, according to the methods available, whose result will be constituted as full evidence.

**Article 10.- Sanctions regime.** The Competent National Authority of each Country Member will proceed with the application of sanitary security measures and sanctions to which there is place for the breach of the present Technical Regulation Andean, as established in Chapter VII "On Health Surveillance" of the Decision 833 and its amendments or the regulations that replace it.

**Article 11.- Entry into force.** These Andean Technical Regulations will enter effective May 27, 2020.

### SUPPLEMENTARY PROVISION

**ONLY. - These Andean Technical Regulations will be reviewed at least once every**

five (5) years, with the purpose of updating or repealing it, or when the conditions that gave rise to change or disappear.

Given in the city of Lima, Peru, on the seventeenth day of the month of December of year two one thousand nineteen.

*Jorge Hernando Pedraza*  
**General secretary**

**APPENDIX 1**  
**PRODUCTS COVERED IN THE ANDEAN TECHNICAL REGULATION ON**  
**MICROBIOLOGICAL TECHNICAL SPECIFICATIONS OF PRODUCTS**  
**COSMETICS (ACCORDING TO DECISION 812)**

<b>Code</b>	<b>Merchandise description</b>	<b>Observations</b>	
3303.00.00	Perfumes and toilet waters		
<b>33.04</b>	<b>Beauty, makeup and hair preparations skin care, except medications, including antisolares preparations and tanning machines; manicure preparations and pedicures.</b>		
3304.10.00	- Preparations for the make-up of lips	Only cosmetic product	for
3304.20.00	- Preparations for eye makeup	Only cosmetic product	for
3304.30.00	- Manicure or pedicure preparations - The others:		
3304.91.00	- - Powders, including compact powders		
3304.99.00	- - The others	Only cosmetic product	for
<b>33.05</b>	<b>Hair preparations.</b>		
3305.10.00	- Shampoos	Only cosmetic product	for
3305.20.00	- Preparations for waving or straightening permanent		
3305.30.00	- Hair spray		
3305.90.00	- The others	Only	for

			cosmetic product
33.06	<b>Oral or dental hygiene preparations, including powders and creams for denture adhesion; thread used for cleaning the interdental spaces (thread dental), in individual packages for sale to the retail.</b>		
3306.10.00	- Toothpastes	Only	for cosmetic product
3306.90.00	- Others	Only	for cosmetic product
33.07	<b>Shaving preparations or before or after shave, body deodorants, bath preparations, depilatories and other perfumery, toilet preparations or cosmetic, not expressed or included elsewhere; preparations room deodorants, whether or not perfumed, even if they have disinfecting properties.</b>		
3307.10.00	- Preparations for shaving or before or After shave		

Code	Merchandise description	Observations	
3307.20.00	- Body deodorants and antiperspirants		For products only cosmetics
3307.30.00	- Scented salts and other preparations for the bathroom	Only	for cosmetic product
3307.90	- Others:		
3307.90.90	Others	Only	for cosmetic product
34.01	<b>Soap; organic products and preparations tensed actives used as soap, in bars, loaves, pieces or die-cut pieces or molded, even if they contain soap; organic products and preparations skin wash surfactants, liquids or cream, put up for retail sale minor, even if they contain soap; paper, wadding, felt and non-woven fabric, impregnated, coated or covered with soap or detergents</b>		
	<b>- Organic soap, products and preparations surfactants, in bars, breads, pieces or pieces die-cut or molded, and paper, wadding, felt and non-woven fabric, impregnated, coated or covered in soap or detergents:</b>		
3401.11.00	- - Of toilet (not including the medicinal ones)		
3401.20.00	- Soap in other forms	Only	for cosmetic product
3401.30.00	- products and preparations surfactants for washing skin, liquids or cream, put up for retail sale, even if they contain soap	Only	for cosmetic product
38.08	<b>Insecticides, rodenticides and other anti-rodents, fungicides, herbicides, inhibitors of germination and growth regulators of plants, disinfectants and products similar, presented in forms or containers for retail sale, or as preparations or items such as tapes, wicks and candles, sulfur, and papers fly swatter.</b>		
	- Others:		
3808.91	- - Insecticides:		

3808.91.14 - - - -	Containing permethrin or cypermethrin or other synthetic substitutes for pyrethrum (pyrethroids), except those mentioned in Note 2 of subheading of this Chapter	Only cosmetic product	for
3808.91.19 - - - -	Others	Only cosmetic product	for
- - -	Others:		
3808.91.91 - - - -	Containing natural pyrethrum (pyrethrin)	Only cosmetic product	for

<b>Code</b>	<b>Merchandise description</b>	<b>Observations</b>	
3808.91.97 - - - -	Containing permethrin or cypermethrin or other synthetic substitutes for pyrethrum (pyrethroids), except those mentioned in Note 2 of subheading of this Chapter	Only cosmetic product	for
3808.91.99 - - - -	Others	Only cosmetic product	for

Note: Cosmetic products must comply with the definition of community regulations.