



**Association of South East Asian Nations (ASEAN)**

# ASEAN GUIDELINES ON LIMITS OF CONTAMINANTS FOR COSMETICS

RELEASE VERSION 3.0

## DOCUMENT INFORMATION

This version was adopted at the 26th ASEAN Cosmetic Scientific Body (ACSB) Meeting 2<sup>nd</sup>-3<sup>rd</sup> May 2017, Siem Reap, Cambodia and endorsed at the 26<sup>th</sup> ASEAN Cosmetic Committee (ACC) MEETING 4<sup>th</sup> - 5<sup>th</sup> May 2017, Siem Reap, Cambodia.

The document was updated following the 30<sup>th</sup> ACSB Meeting ,18-19 June 2019, Nay Pyi Taw, Myanmar.

Version No.	History of adoption and endorsement		Reasons
	ACSB adoption date	ACC endorsement date	
0	7th ACSB Meeting 12 June 2007	8th ACC Meeting 13 – 14 June 2007	- Adopted ASEAN Microbiological Limits
0	8th ACSB Meeting 10 - 11 December 2007	9th ACC Meeting 12-13 December 2007	- Set Limit of Heavy Metal Contamination including Hg, Pb & As
0	22nd ACSB Meeting 26-27 May 2015	22nd ACC Meeting 28th – 29th May 2015	- Set limit of Cadmium into the Limits of Heavy Metal Contamination - Proposal to make Guidelines to incorporate all set limits
1	23 <sup>rd</sup> ACSB Meeting 25 November 2015	Under review	First draft
2	26 <sup>th</sup> ACSB Meeting 2-3 May 2017	Adopted	- Text corrections and clarifications
3	30 <sup>th</sup> ACSB Meeting 18-19 June 2019	For endorsement	- Set limits and timings for 1,4 Dioxane

## INTRODUCTION

The ASEAN Guidelines on Limits of Contaminants for Cosmetics are developed by taking safety and quality requirements into consideration. The limits set are guidelines for use during the finished product analysis performed as part of in-market inspection.

This document may be used as a reference by cosmetic companies in the manufacture of their products. Nevertheless, more stringent limits may be applied as appropriate.

Microbial contaminants could be derived from:

- The nature of the product whether it is a pure compound, an extract, raw material or its combination.
- The manufacturing process
- The distribution process

To determine the limits of microbial contaminants the following should be taken into consideration:

- The area of application (e.g. eye area and mucous membranes)
- Type of consumers/the target population of the products

Other limits of contaminants may be reviewed and included into the guideline as deemed necessary.

Heavy metals are found naturally in the environment and in rocks, soil and water, and may therefore be found in pigments and other raw materials.

Heavy metal contaminants could be derived from:

- The quality & purity of raw materials:
- The manufacturing process.
- The quantity of raw material used.

Heavy metals cannot be deliberately added as they are individually listed in Annex II, unless their presence is in trace amounts and is technically unavoidable in good manufacturing practice.

## OBJECTIVE

The objective of these guidelines is to provide guidance on the limits of microbial and heavy metal contaminants to ensure the quality and safety of marketed cosmetics.

### ASEAN LIMITS OF CONTAMINANTS FOR COSMETICS

#### 1. LIMITS OF MICROBIAL CONTAMINANTS

The limit used is based on the current data and information and the latest scientific update in cosmetics to ensure consumer safety. The limits may change as needed according to the latest compendium or safety information on microbial contaminants.

Table 1. ASEAN Microbiological Limits

	Products for children under 3 years, eye area and mucous membranes	Other products
<b>Total Aerobic Mesophilic Microorganisms (Bacteria, Yeast &amp; Molds)</b>	<b>=&lt; 500 cfu/g or cfu/ml</b>	<b>=&lt; 1000 cfu/g or cfu/ml</b>
<b><i>P. aeruginosa</i></b>	Absent in 0.1g or 0.1ml test sample	Absent in 0.1g or 0.1ml test sample
<b><i>S. aureus</i></b>	Absent in 0.1g or 0.1ml test sample	Absent in 0.1g or 0.1ml test sample
<b><i>C. albicans</i></b>	Absent in per 0.1g or 0.1ml test sample	Absent in 0.1g or 0.1ml test sample

The list is not necessarily exhaustive. It may be necessary to test for other micro-organisms\* depending on the nature of the starting materials and the manufacturing process.

\*Note: Thailand will continue to perform an additional test for Clostridia spp. on products containing crude herbal extracts due to local concerns. The requirement is that such products test negative for *Clostridium spp.*

## 2. LIMITS OF HEAVY METALS:

Maximum limits of heavy metals:

Heavy Metals	Limits
Mercury (Hg)	NMT 1 mg/kg or 1 mg/L (1 ppm) when tested by ASEAN Cosmetic Method
Lead (Pb)	NMT 20mg/kg or 20 mg/L (20 ppm) when tested by ASEAN Cosmetic Method
Arsenic (As)	NMT 5mg/kg or 5 mg/L (5 ppm) when tested by ASEAN Cosmetic Method
Cadmium (Cd)	NMT 5 mg/kg or 5 mg/L (5 ppm)** when tested by ASEAN Cosmetic Method

The test method for Mercury, Lead, Arsenic and Cadmium follows ACMTHA05 that has been adopted in the 8<sup>th</sup> ACSB Meeting (10 - 11 December 2007, Viet Nam).

Note:

\*\*Due to special circumstances such as national regulatory requirements, the limit of cadmium in the Thailand is 3 mg/kg or 3 mg/L (3 ppm).

## 3. LIMITS OF TRACE IMPURITIES

Trace Impurities	Limits
1,4 – Dioxane	NMT 25 mg/kg or 25 mg/L (25ppm), effective 19 June 2020 NMT 10mg/kg or 10mg/L (10ppm), effective 19 June 2023

As adopted in the 30<sup>th</sup> ACSB Meeting (18-19 June 2019, Myanmar)

## GLOSSARY

NMT: Not More Than

CFU: Colony Forming Unit