



ASEAN COSMETIC DIRECTIVE (ACD) OVERVIEW

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ACD OBJECTIVES

- Harmonization of technical requirements.
- AHCRS signed by the Government of the 10 Member Countries in September 2003 and implementation was between 2008-2011.
- Being a Directive, it must be transposed into local regulations.
- The ACD was modeled after the EU Cosmetic Directive 6th amendment.

ACD REQUIREMENTS

- Safety of products as per article 3: “products must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use”;
- Quality of products as per article 8.c: “method of manufacture complying with the good manufacturing practice as laid down in the ASEAN Guidelines for Cosmetic Good Manufacturing Practice appearing as Appendix VI”;

ACD REQUIREMENTS

- Efficacy of products as per article 8.f: “supporting data for claimed benefits of cosmetic products should be made available; to justify the nature of its effect”;

SAFETY

- Safety assessment is mandatory, a copy of the report must be in the PIF:
 - Summary in Part 1;
 - Full report in Part 4;
- Health related consumer complaints must be in the PIF:
 - Summary in Part 1;
 - Full report in Part 4:

QUALITY

- GMP/GDP is a mandatory requirement!
- Compliance to ASEAN GMP Guidelines (or ISO 22716:2007) is mandatory, certification by an accredited body is not mandatory;
- Attestation of compliance from the manufacturing site must be in the PIF part 1;
- GMP/GDP compliance is part of the product safety;

PRODUCT INFORMATION FILE: PIF

- Article 8 lists all the requirements of the PIF;
- The PIF Guidelines explains how to organize the PIF and how and when the Authorities can and will audit;

LABELING

- Appendix II of the ACD details the labeling requirements;
- The requirements are similar to EU requirements. Only major difference relates to animal ingredients (bovine, ovine or porcine).

CLAIMS

- Appendix III of the ACD details the Claims Guidelines;

APPENDIX III: CLAIM GUIDELINES

- Only cosmetic claimed benefits;
- No medicinal or therapeutic;
- Justified by technical data and/or cosmetic formulation or preparation;
- Text name, trademarks, pictures, figurative or other signs shall not be misleading;
- Watch for the web site!

INGREDIENTS

- Annexes II to VII control some ingredients that are either banned, restricted or must be used for a specific purpose (colors, preservatives, UV filters).

ANNEX II

List of Substances which **must not** form part of the composition of Cosmetic Products i.e., substances which are banned in cosmetic products (Negative List);

Substance	CAS Number	Ref. No
Aminophylline	317-34-0	A1136
Theophylline	58-55-9	A1137
Methylene chloride (Dichloromethane)	75-09-2	A1138
Chlorofluorocarbons		A1139
Diethylene glycol	111-46-6	A1140
Azelaic acid	123-99-3	A1141
Bimatoprost	155206-00-1	A1142
N-5-Chlorobenzoxazol-2-yl acetamide	8024-12-2	1
β-Acetoxyethyl trimethylammonium hydroxide (acetylcholine and its salts)	60-31-1	2
Deanol aceglumate	3342-61-8	3
Spironolactone	52-01-7	4
[4-(4-Hydroxy-3-iodophenoxy)-3,5-diodophenyl] acetic acid and its salts		5
Methotrexate	59-05-2	6
Aminocaproic acid and its salts	60-32-2	7
Cinchophen, its salts, derivatives and salts of these derivatives	132-60-5	8
Thyropropic acid and its salts	51-26-3	9
Trichloroacetic acid	76-03-9	10
Aconitum napellus L. (leaves, roots and galenical preparations)		11
Aconitine (principal alkaloid of Aconitum napellus L.) and its salts	302-27-2	12
Adonis vernalis L. and its preparations		13
Epinephrine	51-43-4	14

ANNEX III

List of substances which cosmetic products must not contain except subject to restriction and conditions laid down i.e., list of restricted substances;

For each substance there is a field of application and/or use; a maximum authorized concentration in the finished product, other limitations as well as conditions of use and warning which must be printed on the label;

Ref #	Substance	Restrictions			Conditions of use and warning which must be printed on the labels
		Field of application and/or use	Maximum authorised concentration in the finished cosmetic product	Other limitations and requirements	
a	B	C	d	e	f
2b	Thioglycolic acid esters	Hair waving or straightening products: - General use - Professional use	- 8% ready for use pH 6-9.5 - 11% ready for use pH 6-9.5 Percentages calculated as thioglycolic acid.	The directions for use drawn up in the national or official language(s) must obligatorily incorporate the following sentences: <ul style="list-style-type: none"> May cause sensitisation in the event of skin contact. Avoid contact with eyes. In the event of contact with eyes, rinse off with plenty of water and seek medical advice. Wear suitable gloves. 	- Contains thioglycollate. - Follow the instructions. - Keep out of reach of children. - For professional use only.
3	Oxalic acid, its esters and alkaline salts	Hair care products	5%		- For professional use only
4	Ammonia		6% calculated as NH ₃		- Above 2%: contains ammonia
5	Tosylchloramide sodium		0.2%		
6	Chlorates of alkali metals	(a) Toothpaste (b) Other uses	(a) 5% (b) 3%		

ANNEX IV

List of coloring agents allowed for use (positive list).

Each color is described by its color index and fields of allowed application are listed:

1. All cosmetic products;
2. All products except those to be applied in the vicinity of the eyes;
3. Allowed exclusively in products to come in contact with the mucous membrane;
4. Allowed exclusively in products intended to come in contact briefly with the skin;

Colour Index Number or Denomination	Colour	Field of application				Other limitations and requirements
		1	2	3	4	
10006	Green				X	© Seers Consulting
10020	Green			X		
10316 ⁽²⁾	Yellow		X			
11680	Yellow			X		
11710	Yellow			X		
11725					X	
11920		X				
12010	Red			X		

ANNEX VI

List of Preservatives which cosmetic products may contain (positive list);

Each substance is described with its maximum authorized concentration, limitations/requirements and conditions for use/warnings;

Substances with a (+) can be used at a different concentration if they are used for a different purpose than to preserve the product

ANNEX VII

List of UV Filters which cosmetic products may contain (positive list).

Reference number	Substance	Maximum Authorised concentration	Other limitations and requirements	Conditions of use and warnings which must be printed on the label
a	b	c	D	e
A28	Methyl anthranilate	5 %		Do not stay too long in the sun, even while using a sunscreen product
A29	Zinc oxide	25 % in sunscreen products		Do not stay too long in the sun, even while using a sunscreen product
1	Deleted			
2	N,N,N-Trimethyl-4-(2-oxoborn-3-ylidene methyl) anilinium methyl sulphate	6%		Do not stay too long in the sun, even while using a sunscreen product
3	Homosalate ()	10%		Do not stay too long in the sun, even while using a sunscreen product
4	Oxybenzone ()	10%		Contains oxybenzone ¹ Do not stay too long in the sun, even while using a sunscreen product

INSTITUTIONS

- ACC: ASEAN Cosmetic Committee tasked with coordination, review and monitoring of the implementation of the Directive. Composed by representatives of each Member State, ASEAN Secretariat and ASEAN Cosmetic Association (ACA);
- ACSB: ASEAN Cosmetic Scientific Body tasked with making recommendations to ACC on safety, technical and scientific matters (e.g., modification of annexes II to VII, borderline products);

COMPANY'S RESPONSIBILITIES

The company or person responsible for placing the cosmetic products in the market shall:

- ensure that the product will not cause damage to human health when applied under normal or reasonably foreseeable conditions of use (safety assessment);
- notify the regulatory authority before the product is placed on the market: one notification per country.
- keep the products technical and safety information readily accessible to the regulatory authority (PIF: Product Information File, article 8) in each country.

Companies must have adequate knowledge/experience of the requirements of the Directive

VOICE OF THE INDUSTRY

LOCAL

- The Industry association is a partner to the Regulatory Authorities;
- the Association represents its members but also the whole industry: cosmetic manufacturers, distributors, suppliers (raw materials, packaging, consultants, etc);

REGIONAL

- ACA the ASEAN Cosmetic Association is the partner;
- ACA has a delegation participating in the ACC and the ACSB;
- ACA comprises the following associations:
 - Indonesia PERKOSMI;
 - Malaysia FMM CTIG;
 - Myanmar MCA;
 - Philippines CCIP;
 - Singapore CTFAS;
 - Thailand TCMA;
 - Vietnam VOCA;

THANK YOU