



Cosmetic Legislation



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European Cosmetics legislation

Previously.....

European Cosmetics Directive (76/768/EEC)

.....as amended

**The UK Cosmetic Products (Safety) Regulations 2008
(SI No. 1284)**

.....as amended



NOW!

**European Cosmetics Regulation
(Regulation (EC) No. 1223/2009)**

Full implementation from 11 July 2013

Directly applicable in all 28 European Member States



EC Cosmetics Regulation 1223/2009

- 🌀 In-market Control Remains

- 🌀 No Pre-registration or Pre-authorisation

- 🌀 **Implementation and Enforcement:**

European Member States' Competent Authorities

UK

- 🌀 **Implementation:**

BIS (Department for Business, Innovation and Skills)

- 🌀 **Enforcement:**

Trading Standards

Cosmetic Legislation: Safety



Simply:



Product must be SAFE



This must be demonstrated



**Adequate information must be provided to
Competent Authorities and consumer**



Cosmetics Regulation: Articles

- 1: Scope and Objective
- 2: Definitions
- 3: Safety
- 4: Responsible Person
- 5: Obligations of the responsible person
- 6: Obligations of the distributors
- 7: Identification within the supply chain
- 8: Good manufacturing practice
- 9: Free movement
- 10: Safety assessment
- 11: Product information file
- 12: Sampling and analysis
- 13: Notification
- 14: Restrictions in the Annexes
- 15: CMRs
- 16: Nanomaterials
- 17: Traces
- 18: Animal testing
- 19: Labelling
- 20: Product Claims
- 21: Access to information for the public
- 22: In-market control
- 23: Communication of serious undesirable effects
- 24: Information on substances
- 25: Non compliance by the responsible person
- 26: Non compliance by the distributors
- 27: Safeguard clause
- 28: Good administrative practices
- 29: Cooperation between competent authorities
- 30: Cooperation regarding verification of PI file
- 31: Amendment of the Annexes
- 32: Committee
- 33: Glossary of common ingredient names
- 34: Competent authorities, poison control centres
- 35: Annual report on animal testing
- 36: Formal Objection against Harmonised Standards
- 37-40: Penalties; Repeal; Transitions; Dates

Definition: Article 2

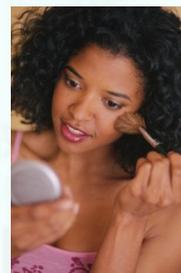
A 'cosmetic product' shall mean any substance or mixture intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to ...



Clean



Perfume



Change the appearance



Correct body odour

Protect or keep in good condition



Main premise – SAFETY!

Article 3:

A cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use, taking account, in particular, of the following:

- (a) presentation;*
- (b) labelling;*
- (c) instructions for use and disposal;*
- (d) any other indication or information provided by the responsible person.*



Ingredients

- ☿ In theory **any** substance may used.....
- ☿ Provided it is **safe**
- ☿ **Except** where banned or restricted, or
- ☿ Subject to positive lists

Banned Substances

Annex II

List of prohibited substances

Restricted Ingredients

Annex III

Restricted substances

Annex IV

Positive list of colours

Annex V

Positive list of preservatives

Annex VI

Positive list of UV filters



Labelling

- ❧ Company name and address (EU)
 - ❧ Country of origin (if imported)
 - ❧ Nominal content (weight or volume)
 - ❧ Date of minimum durability ($\leq 30M$): BBE date or 
- OR**
- PAO ($> 30M$): 
- ❧ Conditions of use and Warnings
 - ❧ Batch number
 - ❧ Product Function (unless clear)
 - ❧ Ingredient list (INCI)



Product Information File (PIF)

- 🌀 Product description
- 🌀 Cosmetic Product Safety Report
- 🌀 Proof of effect
- 🌀 Animal testing data
- 🌀 Method of manufacture - statement of GMP

Access?

- 🌀 Competent Authority where PIF held
- 🌀 **UK** – Trading Standards



Safety Assessment

Article 10 and Annex I

 **Cosmetic Product Safety Report**

 **CPSR is in 2 parts:**

Part A, Cosmetic Product Safety Information

Part B, Cosmetic Product Safety Assessment

..... there shall be inter alia a specific assessment for cosmetic products intended for use on children under the age of three and for cosmetic products intended exclusively for use in external intimate hygiene



Safety Assessment

1. Quantitative & Qualitative composition
2. Physical/Chemical Characteristics and Stability
3. Microbial Quality
4. Impurities, traces in the product and information on the packaging material
5. Normal & Reasonably Foreseeable Use
6. Exposure to the product
7. Exposure to the ingredients
8. Toxicological profile of the ingredients
9. Undesirable effects to the product and other relevant products
10. Other information on the product



Claims - PIF

Proof of Effect

- Information is required to support claimed effects, where justified by the nature of the effect or product
- Only required where a claimed effect is in addition to that which is obvious
- Sufficient documentation
- Summary of protocol used

Claim Substantiation

- Literature references
- Supplier information
- Laboratory/Consumer/Clinical studies



Claims: *Article 20 (2)*

Common Criteria for Cosmetic Claims Regulation

- Legal compliance
- Truthfulness
- Evidence support
- Honesty
- Fairness
- Allow informed decisions



Where to find information?

-  *Information Centre of the CTPA public site: ctpa.org.uk*
- www.ctpa.org.uk/legislation for:
 - Cosmetics Regulation (EC) No. 1223/2009
 - Government Guidelines to the UK legislation
- www.ctpa.org.uk/regulation for:
 - Supplying or Manufacturing a Cosmetic Product
 - Borderlines
- www.ctpa.org.uk/getting_help for:
 - Requesting information on independent consultants e.g. safety assessors



One more plug.....

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Science Behind Products

- Antiperspirants & deodorants
- Babycare
- Fragrance
- Hair colorants and haircare
- Make-up
- Male grooming
- Oralcare
- Packaging
- Skincare
- Sunscreens

Advice

- What's in my cosmetic?
- Your safety matters to us
- Inner beauty - how we feel
- Caring for future generations

Information

- Who are we?
- Media centre
- Sign-up for alerts and newsletters
- Contact Us
- Sitemap

Worried about reactions to hair dye?
20 February 2015
For more information..... [read the full article](#)

Be aware of illegal and counterfeit products
12 February 2015
The packaging and look of counterfeit products can be almost impossible to tell from the real thing..... [read the full article](#)

Being sun safe
What is the legacy of sun damage?

Black Henna
There is no such thing as 'black henna'.

Dr Barbara Hall speaking on chemicals, cosmetics and misconceptions at #Sciencebehindbeauty event 12 May
<http://t.co/lVnMYP0Y9> 11 May 2015 10:21

Still time to register for #Sciencebehindbeauty media event and networking reception on 12 May
<http://t.co/lVnMYP0Y9> 08 May 2015 16:07

What's in my cosmetic?
Baffled by technical terms and jargon? Use this section to understand what it all means. Cannot find what you are looking for? Use the contact us for help.
Select a topic alphabetically:

Hot topics

- > Allergy advice
- > Animal testing
- > 'Black henna' temporary tattoos
- > Cosmetic claims
- > Counterfeit products
- > Endocrine disruptors
- > Hair colorants and allergy

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The science behind beauty

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