EU regulatory framework for marine raw materials
EU REGULATIONS

- EU Cosmetics Regulation

of 30 November 2009
on cosmetic products

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT
AND OF THE COUNCIL
of 18 December 2006

concerning the Registration, Evaluation, Authorisation and
Restriction of Chemicals (REACH), establishing a European Chemicals Agency.

- Registration, Evaluation and Authorization of Chemicals (REACH)

of 16 December 2008
on classification, labelling and packaging of substances and mixtures, amending and repealing

- Classification, Labeling and Packaging (CLP)
Basic principles:

- Determining the safety of your ingredient
- Determining the INCI name of your ingredient
- Preparing the technical dossier Ingredient Dossier, (CID)

✓ Efficacy studies & claims substantiation
Basic principles:

- Determining the safety of your ingredient
- Determining the INCI name of your ingredient
- Preparing the technical dossier Ingredient Dossier, (CID)

Efficacy studies & claims substantiation
EU REGULATORY REQUIREMENTS - SAFETY

........ according to EU Regulation No 1223/2009

«a cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use» [Article 3]

«Safety is based upon safe ingredients (toxicological profile, Chemical, structure, exposure» [Article 10 & 11]

«The responsible person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product undergone a safety assessment on the basis of the relevant information and a cosmetic product safety report is set up» [Article 10 & 11]

COSMETIC PRODUCT SAFETY REPORT (CPSR) IS MANDATORY FOR EVERY COSMETIC PRODUCT
## COSMETIC PRODUCT SAFETY REPORT, (CPRS)

### PART A: SAFETY INFORMATION

- Quantitative and qualitative composition
- Physical, chemical characteristics, and stability
- Microbiological specifications
- The impurities, traces, information about the packaging material
- **Microbiological and toxicological specifications of the raw materials**
- Normal and reasonably foreseeable use
- Exposure to the cosmetic product and substances
- Others

### PART B: SAFETY ASSESSMENT

- Reasoning/Assessment conclusion
- Labelled warnings & instructions of use

Manufacturer is responsible for the evaluation of the relative data (MSDS-TDS-CID)
Safety Evaluation of Botanical Cosmetic Ingredients

«Botanical raw material» is a component that originates from any part or parts of a plant / herb / shrub / tree, or extracts thereof (includes plant juices, oils, etc.). Algae, and preparations or extracts thereof also included under the definition.

Q1. Is the ingredient well characterized?

Q2. Is there sufficient safety data to cover the cosmetic use?
Q1. Is the ingredient well characterized?

Appropriate Characterization includes:

- Plant-derived Ingredient Identification
- Chemical Characterization
- Specifications
EU REGULATORY REQUIREMENTS - SAFETY

- Plant-derived Ingredient Identification
  - Source of botanical raw material (plant/algea family, genus, species, common names)
  - Part(s) of the plant/algea used
  - Geographic origin (continent, country, region)
  - Cultivar
  - The primary processes (drying, fermentation,...)
  - Extraction method/ preservation system
EU REGULATORY REQUIREMENTS - SAFETY

- Chemical Characterization
  - Chemical identity
    e.g.: Form & Molecular weight
  - Content of nutrients
    e.g.: Proteins, Fats, Lipids & Fatty acids, Carbohydrates (simple & complex), Vitamins, Minerals
  - By-products, Impurities
    e.g.: Mycotoxins, Pesticides, Residual Solvents, Heavy Metals
**EU REGULATORY REQUIREMENTS - SAFETY**

*Regulation (EC) No 1223/2009*

**ANNEX II, Ingredients banned in cosmetics**

List of heavy metals banned in cosmetics

<table>
<thead>
<tr>
<th>No</th>
<th>Chemical name</th>
<th>CAS</th>
<th>EC</th>
</tr>
</thead>
<tbody>
<tr>
<td>97</td>
<td>Chromium; chronic acid and its salts</td>
<td>7440-47-3</td>
<td>231-157-5</td>
</tr>
<tr>
<td>69</td>
<td>Lead and its compounds</td>
<td>7439-92-1</td>
<td>231-100-4</td>
</tr>
<tr>
<td>43</td>
<td>Arsenic and its compounds</td>
<td>7440-38-2</td>
<td>231-148-6</td>
</tr>
<tr>
<td>221</td>
<td>Mercury and its compounds, except those special cases included in Annex V (preservative 0.007% of Hg)</td>
<td>7439-97-6</td>
<td>231-106-7</td>
</tr>
<tr>
<td>68</td>
<td>Cadmium and its compounds</td>
<td>7440-43-9</td>
<td>231-152-8</td>
</tr>
<tr>
<td>40</td>
<td>Antimony and its compounds</td>
<td>7440-35-0</td>
<td>231-149-5</td>
</tr>
<tr>
<td>297</td>
<td>Selenium and its compounds with the exception of selenium disulphide under the conditions set out under reference No 49 in Annex II (antidandruff 1%)</td>
<td>7782-49-2</td>
<td>231-957-4</td>
</tr>
</tbody>
</table>
### EU REGULATORY REQUIREMENTS - SAFETY

#### REGULATION ON COSMETICS IN GERMANY

**JULY 2017**

<table>
<thead>
<tr>
<th>Element</th>
<th>Cosmetic products in general (mg/kg)</th>
<th>Toothpaste (mg/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead (Pb)</td>
<td>2.0&lt;sup&gt;a&lt;/sup&gt;</td>
<td>0.5</td>
</tr>
<tr>
<td>Cadmium (Cd)</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>Mercury (Hg)</td>
<td>0.1</td>
<td>0.1</td>
</tr>
<tr>
<td>Arsenic (As)</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>Antimony (Sb)</td>
<td>0.5</td>
<td>0.5</td>
</tr>
</tbody>
</table>

<sup>a</sup> For the products make-up powder, rouge, eye shadow, eye liner: 5 mg/kg
Specifications

- Physical state
  
  e.g.: powder, solution, suspension

- Microbiological Quality
  
  Total Aerobic Microorganisms: < 100 CFU/ml

  Specified Pathogens: Absence

- Allergens

  REG. 1223/2009, ANNEX III, Ingredients restricted in cosmetics
**EU REGULATORY REQUIREMENTS - SAFETY**

*Regulation (EC) No 1223/2009*

**ANNEX III**, Ingredients restricted in cosmetics

List of 26 substances responsible for allergy to cosmetics

<table>
<thead>
<tr>
<th>RICI name</th>
<th>CAS number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amyl cinnamal</td>
<td>122-40-7</td>
</tr>
<tr>
<td>alpha-Amyl cinnamyl alcohol</td>
<td>101-85-9</td>
</tr>
<tr>
<td>Anise alcohol</td>
<td>105-13-5</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
</tr>
<tr>
<td>Benzyl benzoate</td>
<td>120-51-4</td>
</tr>
<tr>
<td>Benzyl cinnamate</td>
<td>103-41-3</td>
</tr>
<tr>
<td>Benzyl salicylate</td>
<td>118-58-1</td>
</tr>
<tr>
<td>Butyl phenyl methyl propional</td>
<td>80-54-6</td>
</tr>
<tr>
<td>Cinnamal</td>
<td>104-55-2</td>
</tr>
<tr>
<td>Cinnamyl alcohol</td>
<td>104-54-1</td>
</tr>
<tr>
<td>Citral</td>
<td>5392-40-5</td>
</tr>
<tr>
<td>Citronellol</td>
<td>106-22-9</td>
</tr>
<tr>
<td>Coumarin</td>
<td>91-64-5</td>
</tr>
<tr>
<td>Eugenol</td>
<td>97-53-0</td>
</tr>
<tr>
<td>Farnesol</td>
<td>4602-84-0</td>
</tr>
<tr>
<td>Geraniol</td>
<td>106-24-1</td>
</tr>
<tr>
<td>Hexyl</td>
<td>101-86-0</td>
</tr>
<tr>
<td>Cinnamal</td>
<td></td>
</tr>
<tr>
<td>Hydroxy citronellal</td>
<td>107-75-5</td>
</tr>
<tr>
<td>Hydroxy citronellal - cyclohexene carboxy aldehyde</td>
<td>31906-04-4</td>
</tr>
<tr>
<td>Iseteugenol</td>
<td>97-54-1</td>
</tr>
<tr>
<td>Alpha-terpineol methyl ionone</td>
<td>127-51-9</td>
</tr>
<tr>
<td>d-Limonene</td>
<td>5989-27-5</td>
</tr>
<tr>
<td>Linalool</td>
<td>78-70-6</td>
</tr>
<tr>
<td>Methyl-2-ocysteate</td>
<td>111-12-6</td>
</tr>
<tr>
<td>Evernia prunastri/vak moss</td>
<td>90028-68-5</td>
</tr>
<tr>
<td>Evernia furfuracea/free moss</td>
<td>90028-67-4</td>
</tr>
</tbody>
</table>
Mandatory declaration on the label

- 0.01% for rinse-off products
- 0.001% for leave-on product

Raw materials must evaluate their “allergen status”
Q2. Is there sufficient safety data to cover the cosmetic use?

http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_190.pdf
General toxicological requirements

1. Acute toxicity (if available)
2. Irritation and corrosivity (skin and eye)
3. Skin sensitisation
4. Dermal / percutaneous absorption
5. Repeated dose toxicity
6. Mutagenicity / genotoxicity
7. Carcinogenicity
8. Reproductive toxicity
9. Toxicokinetics
10. Photo-induced toxicity
11. Human data.
ANIMAL TESTING BAN

Cosmetic Finished Products: Since September 2004
Cosmetic Raw Materials: Since March 2009
Marketing Ban: Since March 2013

\textbf{!} Raw materials must evaluate their safety by using alternative methods

\textbf{!} \textit{in vitro} testing methods should preferentially be used
**EU REGULATORY REQUIREMENTS - SAFETY**

**Validated & Accepted Alternative Methods**

https://eurl-ecvam.jrc.ec.europa.eu/

**in vitro safety test**

2. *Irritation and corrosivity (skin and eye):* EpiDerm (OECD 439) (for skin) / EpiOcular (OECD 492) (for eyes)


10. *Photo-induced toxicity:* 3T3 NRU

**in vivo safety test**

3. *Skin sensitization:* HRIPT (Human Repeated Insult Patch Test)
EU REGULATORY REQUIREMENTS - SAFETY

OTHER KEY POINTS TO TAKE INTO CONSIDERATION

- RESTRICTIONS FOR SUBSTANCES LISTED IN THE ANNEXES OF REG. (EC) No 1223/2009
  - ANNEX II: Ingredients banned in cosmetics
  - ANNEX III: Ingredients restricted in cosmetics
  - ANNEX IV: Colorants allowed in cosmetics
  - ANNEX V: Preservatives allowed in cosmetics
  - ANNEX VI: UV-filters allowed in cosmetics

- RESTRICTIONS FOR SUBSTANCES CLASSIFIED AS CMR, (Carcinogenicity, Mutagenicity, Reproductive), CLP regulation No 1272/2008
  General principle for CMR: use is banned in cosmetic products
OTHER KEY POINTS TO TAKE INTO CONSIDERATION ......

<table>
<thead>
<tr>
<th>No</th>
<th>Chemical name</th>
<th>CAS</th>
<th>EC</th>
</tr>
</thead>
<tbody>
<tr>
<td>47</td>
<td>Benzene</td>
<td>71-43-2</td>
<td>200-753-7</td>
</tr>
<tr>
<td>315</td>
<td>Carbon tetrachloride</td>
<td>56-23-5</td>
<td>200-262-8</td>
</tr>
<tr>
<td>125</td>
<td>Dichloroethanes (ethylene chlorides) e.g. 1,2-Dichloroethane</td>
<td>107-06-2</td>
<td>203-458-1</td>
</tr>
<tr>
<td>1169</td>
<td>1,1,2-Trichloroethane</td>
<td>79-00-5</td>
<td>201-166-9</td>
</tr>
</tbody>
</table>

Residual solvents

Preservatives

ANNEX V

! 57 ARE LISTED
OTHERS NOT ALLOWED
EU REGULATORY REQUIREMENTS

Basic principles:

- Determining the safety of your ingredient
- Determining the INCI name of your ingredient
- Preparing the technical dossier Ingredient Dossier, (CID)

Efficacy studies & claims substantiation
INCI (International Nomenclature of Cosmetic Ingredients)

The declaration of the ingredients on cosmetic finished products must be in accordance with the INCI system [article 10 (1)]

<table>
<thead>
<tr>
<th>Constituant</th>
<th>EN Nom INCI/CTFA - Component INCI/CTFA Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aqua/water</td>
<td></td>
</tr>
<tr>
<td>Butylene glycol</td>
<td></td>
</tr>
<tr>
<td>Alaria Esculenta extract</td>
<td></td>
</tr>
</tbody>
</table>

! New raw materials may need to be registered for INCI name on the Personal Care Products Council, (PCPC).
EU REGULATORY REQUIREMENTS - INCI NAME

Do you need an INCI name?

Does your ingredient has an INCI name?

Yes

Complete SDS, TDS

Don’t Know

No

Check on line sources (Cosing & INCI Dictionary)

Start the INCI application procedure
Basic principles:

- Determining the safety of your ingredient
- Determining the INCI name of your ingredient
- Preparing the technical Cosmetic Ingredient Dossier, (CID)

Efficacy studies & claims substantiation
Cosmetic Ingredient Dossier includes:

- **AT LEAST**
  - The raw data for all the above (evaluating the safety)
  - Technical Data Sheet (TDS)
  - Material Safety Data Sheet (MSDS)
  - Allergen Declarations

- **IN ADDITION**
  - Certificates of Analysis (CoA)
  - Certificates of Conformity
  - Free-From Certificates
  - Efficacy studies
1. Identification
2. Hazard(s) identification
3. Composition/information on ingredients
4. First-aid measures
5. Fire-fighting measures
6. Accidental release measures
7. Handling and storage
8. Exposure control/personal protection
9. Physical and chemical properties
10. Stability and reactivity
11. Toxicological information
12. Ecological information
13. Disposal considerations
14. Transport information
15. Regulatory information
16. Other information
Cosmetic Ingredient Dossier includes:

- **AT LEAST**
  - The raw data for all the above
  - Technical Data Sheet (TDS)
  - Safety Data Sheet (SDS)
  - Allergen Declarations

- **IN ADDITION**
  - Certificates of Analysis (CoA)
  - Certificates of Conformity
  - Free-From Certificates
    - e.g.: Animal Testing, GMO, Iodine, Heavy Metals, etc
Basic principles:

- Determining the safety of your ingredient
- Determining the INCI name of your ingredient
- Preparing the technical Cosmetic Ingredient Dossier, (CID)

✔ Efficacy studies & claims substantiation
EU REGULATORY REQUIREMENTS - EFFICACY

ACTIVE INGREDIENT......

Function
- Moisturizing
- Antiwrinkle
- Antioxidant Effect
- Firming Effect
- Reduction of dark circles
- Smoothes the skin

In vitro studies → Clinical evaluation

Mechanism of action → Proof of efficacy

Recommended concentrations

ex vivo bibliography
Clinical trials
In vivo
In vitro
REACH, Registration, Evaluation and Authorization of Chemicals

*Regulation EC No 1907/2006, 1 June 2007*

- **Applies.....**
  - Substances
  - Preparations (e.g. Cosmetics)

- **Covers.....**
  - Manufacture
  - Placing on the market

- **Requires.....**
  - Registration of raw materials on the EU database

**BASIC PRINCIPLE**

Substances contained in products are safe for human health or the environment.
CLP, Classification, Labeling and Packaging

Regulation (EC No 1272/2008), 20 January 2009

☐ Applies…..
  • Raw materials

☐ Covers…..
  • Classification (hazardous or not)
  • Labeling and packaging

☐ Requires…..
  • MSDS (Material Safety Data Sheet)
  • Special pictograms & safety statements on label

BASIC PRINCIPLE

Customers & workers know the effects of the raw material before using
Thank you

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