



ESSENTIAL OILS: Impact of the chemicals legislation on natural complex ingredients across the natural cosmetics and perfumes market



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CLP revision- impact on MOCs (More than One Component)

the Natural Complex Substances = More than One Component
(so the impact affects the natural ingredients)

Current situation:

- CLP considers NCS as a substance – the safety or the risk is assessed by the knowledge about the substance (note: there is coherence with the concept UVCB in REACH) - REACH dossiers assure the safety for most of the ingredients used in cosmetics
- If CLP classifies as CMR – art 15 of the Cosmetics Regulation bann

Proposed situation by the Commission:

- NCS are called MOCs (More than One Component)
- The assessment is not any more of the substance, but of the isolated constituents of the mixture
- If a constituent is classified as CMR – all the mixtures that contains it above certain amount are clarified as well
- The proposal ignores the safety dossiers and scientific information already existing about the substance.

Let's see some examples



Thymo essential oil



REACH Registro:
[01-2120768771-44](#)

Clasificación Tomillo rojo
como sustancia

(según evaluación y ensayos dossier registro REACH)
Flam. Liq. 4 (H227), Acute Tox. 4 (H302), Asp. Tox. 1 (H304), Skin Corr. 1 (H314), Skin Sens. 1 (H317), Aquatic Chronic 2 (H411)

Substance evaluation
conclude that the product is
safe

MOCS

Constituyente	% aprox.
Thymol	49,5
para-Cymene	18,7 (Rep. 2)
gamma-Terpinene	8,4 (Rep. 2)
Linalool	4,7
Carvacrol	3,6
trans-Caryophyllene	1,9
Beta-Myrcene	1,7
Alpha-Terpinene	1,6
Borneol	1,6
Terpinen-4-ol	1,3
alpha-Pinene	1,1
alpha-Thujene	1,0
Camphene	0,8
alpha-Terpineol	0,6
Limonene	0,4
beta-Pinene	0,3
1,8-Cineole	0,2
...	...

Proposed clasificación
considering constituents

Ignore the toxicology
knowledge about the
substance

Approach through the constituents

Reglamento CLP
Tóxico reproducción

Desencadenan la clasificación en mezcla

Ingrediente	Repr. 1A	Repr. 1B	Repr. 2
Repr. 1A	≥ 0,3%		
Repr. 1B		≥ 0,3%	
Repr. 2			≥ 3%

Clasificación por MOCS:

Flam. Liq. 4	H227
Acute Tox. 4	H302
Asp. Tox. 1	H304
Skin Corr. 1	H314
Skin Sens. 1	H317
Repr. 2	H361
Aquatic Chronic 2	H411



Ylang Ylang



Ac. Es. Ylang Ylang
(Cananga Odorata)



REACH Registro:
[01-2120760178-50](https://ec.europa.eu/reach/reach-register-of-substances)

Clasificación Ylang Ylang
como sustancia

(según evaluación y ensayos dossier
registro REACH)

**Asp. Tox. 1 (H304), Skin Irrit. 2 (H315),
Skin Sens. 1 (H317),
Aquatic Chronic 3 (H412)**

Substance toxicology
evaluation conclude that the
product is safe

MOCS

Constituyente	% aprox.
Linalool	11,5
Benzyl acetate	8,9
p-Methylanisole	8,4 (Repr. 2)
Geranyl acetate	7,8
beta-Caryophyllene	6,7
t-t-alpha-Farnesene	6,0
Benzyl benzoate	5,9
Methyl benzoate	4,2
Benzyl salicylate	2,6
Cinnamyl acetate	2,4
trans-trans-Farnesol	1,8
Geraniol	1,4
3-Methyl-2-butenyl benzoat	0,8
alpha-Pinene	0,6
Eugenol	0,6
3-Methyl-2-butenyl acetate	0,6
Isoeugenol	0,5
...	...

**Proposed clasificación
considering isolated
constituents**

**Ignore the toxicology
knowledge about the
substance**

Approach through the constituents

Reglamento CLP
Tóxico reproducción

Desencadenan la clasificación en mezcla

Ingrediente	Desencadenan la clasificación en mezcla		
	Repr. 1A	Repr. 1B	Repr. 2
Repr. 1A	≥ 0,3%		
Repr. 1B		≥ 0,3%	
Repr. 2			≥ 3%



Clasificación por MOCS:

Asp. Tox. 1	H304
Skin Irrit. 2	H315
Skin Sens. 1	H317
Repr. 2	H361
Aquatic Chronic 3	H412



Aceite esencial Limón



REACH Registro:
[01-2119495512-35](https://ec.europa.eu/reach/reach-register-of-substances)

Clasificación limón
como sustancia
(según evaluación y ensayos dossier
registro REACH)

Flam. Liq. 3 (H226), Asp. Tox. 1
(H304), Skin Irrit. 2 (H315),
Skin Sens. 1 (H317),
Aquatic Chronic 2 (H411)

**SITUACIÓN ACTUAL
EVALUACIÓN INDIVIDUAL
PRODUCTO SEGURO**

MOCS

Constituyente	% aprox.
d-Limonene	68,0
beta-Pinene	11,4
gamma-Terpinene	8,5 (Repr. 2)
alpha-Pinene	1,9
Myrcene	1,6
Geranial	1,3
Neral	0,8
l-β.-Bisabolene	0,6
Neryl acetate	0,4
Terpinolene	0,4
Geranyl acetate	0,3
beta-Caryophyllene	0,2
alpha-Terpineol	0,2
...	...

**Proposed clasificación
considering constituents**

**Ignore the toxicology
knowledge about the
substance**



Reglamento CLP
Tóxico reproducción

Desencadenan la
clasificación en mezcla

Ingrediente	Repr. 1A	Repr. 1B	Repr. 2
Repr. 1A	≥ 0,3%		
Repr. 1B		≥ 0,3%	
Repr. 2			≥ 3%



Clasificación por MOCS:

Flam. Liq. 3	H226	
Asp. Tox. 1	H304	
Skin Irrit. 2	H315	
Skin Sens. 1	H317	
Repr. 2	H361	
Aquatic Chronic 2	H411	Danger



Aceite esencial Anís estrellado

Con MOCS

Anís estrellado



MOCS

Constituyente	% aprox.
trans-Anethole	88
Estragole	3,3
d-Limonene	1,6
Linalool	1,1
alpha-Pinene	0,6
alpha-Phellandrene	0,3
beta-Caryophyllene	0,3
4-Carvomenthenol	0,2
alpha-Terpineol	0,2
cis-Anethole	0,2
delta-3-Carene	0,2
p-Methoxybenzaldehyde	0,2
p-Cymene	0,11
Myrcene	0,1
p-Mentha-1,3-diene	0,1
p-Mentha-1,4-diene	0,1
Terpinolene	0,1

Approach through the constituents

Clasificación MOCs

Skin Sens. 1	H317	GHS08
Muta. 2	H341	GHS07
Carc. 2	H351	Wng
Aquatic Chronic 3	H412	

**Proposed clasificación
considering constituents**

**Ignore the toxicology
knowledge about the
substance**

Los aceites esenciales dejarían de utilizarse en los productos a consumidor por la alerta social que supondría y restricciones por otros reglamentos.

Clasificación NCS (UVCB)

según evaluación y ensayos
dosier registro REACH

No clasificado

Substance evaluation
conclude that the product is
safe



The impact of the proposed method:

More than **400 essential oils would be classified as CMR:**

bergamot, eucalyptus, lemon, lime, rose, lavender...

Estimated, up to 1000 Natural Ingredients currently used in cosmetics



The proposal would ignore the current safety guarantees that the Cosmetics and perfumes have along the value chain, from the crops to the consumer

The value chain of the naturals: full safety guarantees



Crops
Rural areas EU

**Fragrances and
Ingredients companies**

Perfumes & cosmetics
Big & 4000 SMEs

**Retail EU
Consumers**

Sustainable
farming

Strict quality
control

REACH & CLP

Quality and safety

REACH & CLP

IFRA standards
(Allergens, limit
concentrations,...)

Cosmetics Products
Regulation 1223/2009

Quality and safety

**Cosmetics Products
Regulation 1223/2009**
Individual safety dossier

EU Commission
National Authorities

Cosmetovigilance

National
Authorities

SCCS

EU Commission



The value chain of the naturals: full safety guarantees



Crops
Rural areas EU



Fragrances and
Ingredients companies



Perfumes & cosmetics
big & 4000 SMEs



Retail EU
Consumers

Coherence needed for competitiveness and sustainability

Natural
ingredients

**Key for
Green Deal
objectives**



REACH
CLP
IFRA standard
COSMETICS
REGULATION
Product safety
dossier

SCCS

Cosmetovigilance
National Authorities
EU Commission



The presence of the naturals in the market: wide experience



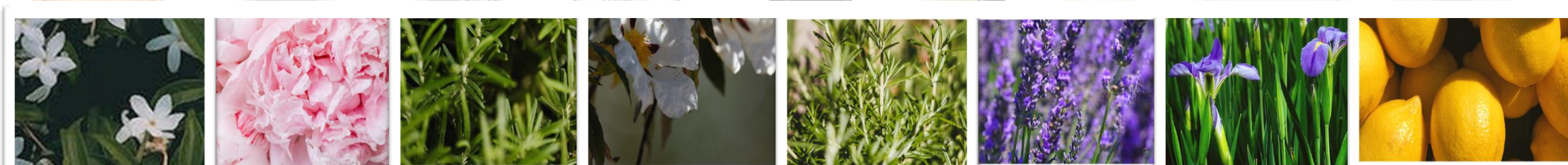
ICONIC perfumes, some as old as 100 years, include natural ingredients.

There are strict controls of raw materials, from the crop to the lab.





Increasing demand for natural ingredients



**Companies are committed to the Green Deal sustainability goals
Naturals are essential for competitiveness and positive impact**



The link between CLP and art 15 Cosmetics Regulation

- Substances classified as CMR according to the CLP Regulation, Automatically **prohibited by art 15** without threshold
- All the impacted natural essential oils and other natural ingredients **banned**
- Very complex exceptional procedure – unfeasible for innumerable substances



The unavoidable impact

- Perfumes and Natural Cosmetics containing these Essential Oils immediately **banned**.
NO transitional periods (unreasonably complex exceptional procedure).
- Iconic perfumes and new launches, new Natural Cosmetics – would have to be **WITHDRAWN from the market, no more sales, no exports...**

World wide impact

- Industry obliged to **reformulate with synthetic ingredients**
- **Green Deal objectives?** Consumer demands of naturals not covered
- **Immediate dramatic impact on next harvest, in Europe and 3rd countries** *Any chance of survival?*





France: the worldwide leader

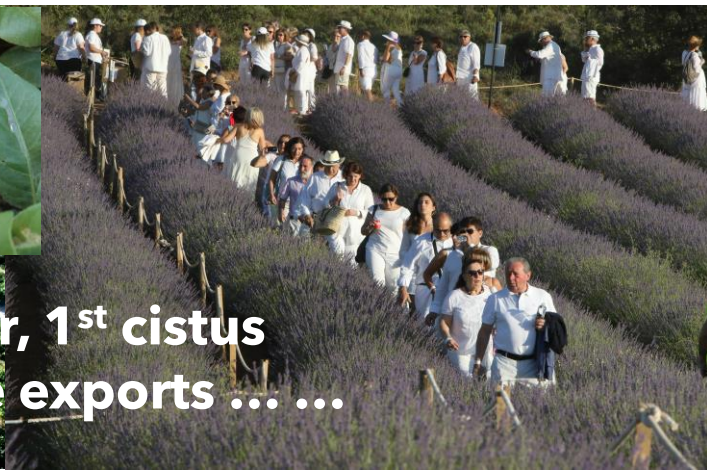


Bulgaria: 45% world rose oil producer , €11 billion

France, Spain, Italy and Bulgaria
the main essential oils and natural extracts producers
But all the rest are **demanding countries for Naturals**



Spain: 2nd world lemon oil producer, 1st cistus producer, lavender, TOP 2 Perfume exports



Italy: 1 world bergamotto oil 80% world production

The socio-economic value of the Perfumes and Cosmetics sector



Worldwide
Beauty market:
€450 billion

Source: Euromonitor



European
Beauty market:
> €80 billion

Source: Euromonitor



**EUROPE
TOP 1
exports**

Beauty
€74.7 billion

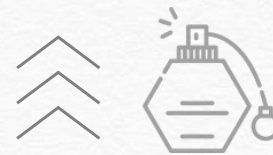


Worldwide
Perfumes market:
€50 billion

(+22% in 2022)



**EU Perfumes
market**
€14.5 billion
30% share



Perfumes export
€15 billion
(+22%)

An assessment of 1320 cosmetic product formulas has shown that 32% of all cosmetic products in a representative cross section of the EU market would contain at least one NCS.

16% of all 'ingredient places' in cosmetic products on the EU market are taken by an NCS.



The socio-economic value of the Perfumes and Cosmetics sector

A competitive, sustainable
and social industry

EU
>250.000 direct employees +
1.750.000 indirect

72%

EU consumers

important or
very important for
hygiene, self-esteem

40 - 85% : essential for self-expression

Ref: *Cosmetics, our essentials for Daily life* - Cosmetics Europe: 6000 EU consumers - 2022





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