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Regulatory Landscape

For Fragranced Products

Key Regulations and Requirements

REACH

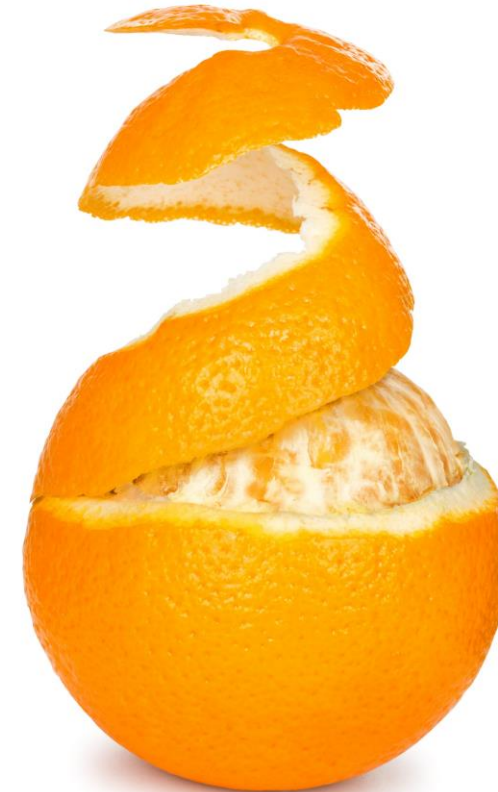
Cosmetics

CLP / GHS

Detergents

Transport

IFRA





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REACH



The REACH Regulation is big with many parts

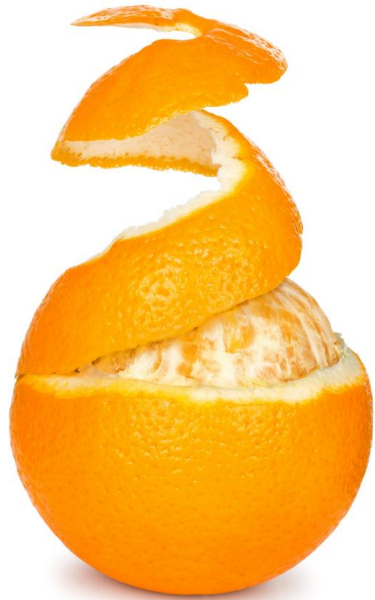
REACH Registration is required for substances if they are manufactured in the EEA (European Economic Area) or imported into the EEA at one tonne per year or more

- There is a specific focus on the safe use of substances
- Some substances are exempt, typically if more stringent legislation exists

The key points are

- Manufacturers / importers must provide extensive safety information about their substances
- This involves re-evaluation of existing information and obtaining new information

[REACH Legislation](#)



Orange oil, as a substance used in a flavour used in a food stuff is exempt from REACH Registration

Orange oil, as a substance used in e.g. fragrance is required to be REACH registered

Orange oil, for flavour or fragrance use, requires a Safety Data Sheet

Orange oil registration includes data gathering / testing which may impact SDS content



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GHS & CLP



CLP is a European regulation which adopts the principles laid down in GHS – the ‘Globally Harmonized System of Classification and Labelling of Chemicals’

CLP is the Classification, Labelling and Packaging of Substances and Mixtures regulation

GHS and CLP are focused on hazard assessment and communication of hazard information via labels and Safety Data Sheets

[CLP](#)

[GHS and the UN](#)

CLP applies to chemical substances and mixtures of chemicals:

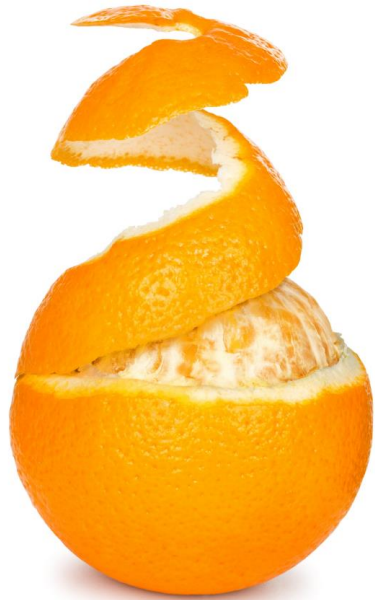
- Includes essential oils and chemicals (substances)
- Includes perfumes, flavours, candles (mixtures)
- There are some exceptions for food, pharmaceuticals and cosmetics supplied to the final consumer in final state

The key aspects of CLP relate to:

- Protecting people's health and safety at work, and protecting the environment
- The key methods are
- Assessing hazards in a specified way
 - Providing information to users or other exposed people via
 - Hazard labels
 - Safety Data Sheets
 - Emergency response data within SDS and to Poison centres

[More about CLP Legislation](#)

CLP Hazard Labels



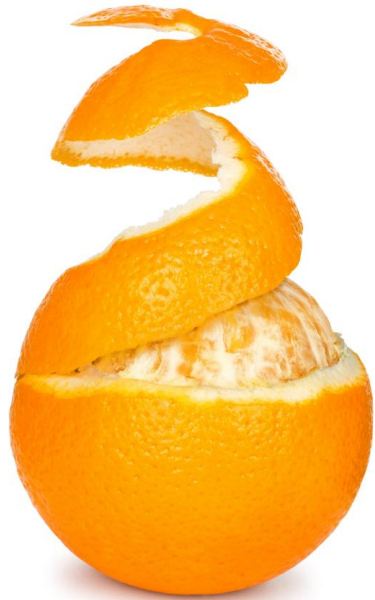
Orange oil, as supplied to an industrial or professional user is required to have a CLP hazard label.

If orange oil is supplied as a cosmetic product to a consumer, then the Cosmetic regulation would apply instead of CLP.

If orange oil is supplied to a consumer (and not as a food or cosmetics), then the CLP regulation would apply. This means a CLP hazard label would be needed, along with CLP compliant packaging.

In the case of Orange oil this means a pack with tactile danger warnings and a child resistant cap.

CLP Hazard Labels



The CLP Label for orange oil contains 4 pictograms and several hazard statements!

CLP / REACH Safety Data Sheets (SDS)



Orange oil, as supplied to an industrial or professional user is required to have a SDS provided before the product is received.

If orange oil is supplied to a consumer for consumer use, then a SDS is not required to be supplied.

If orange oil is supplied as a cosmetic ingredient to a workplace which stores orange oil as a consumer product, a SDS must be provided on request.



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Transport



The [UN Model regulations](#) define criteria of hazards for transport:

- These are harmonised with GHS but not all GHS hazards are transport hazards

These rules apply to products being transported which are hazardous for transport and result in:

- Assignment of UN Numbers and a Proper Shipping Name, a transport category and class
 - Sometimes more than one UN number can be applicable. The most specific UN Number should be allocated
- Labelling and packaging rules

[More about UN Transport](#)

The UN Model regulations impacts different modes of transport in slightly different ways because each transport method has different sensitivities to hazards.

Each method has it's own regulations:

- ADR/RID – Road and Rail
- ICAO – Air transport
- IMDG – Marine / Sea / River



Transport Regulations



The transport hazards for Orange oil relate to the flammability and the environmental hazard.

A typical grade of orange oil would be accompanied by UN 1169 EXTRACTS, AROMATIC, LIQUID and be in Class 3, packing group 3. It's also a marine pollutant.



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Cosmetics



The [cosmetic regulation](#) is focused on the protection and safety of users of cosmetic products:

- Cosmetics are products designed to clean, freshen, condition and/or perfume our bodies (e.g. skin, hair, oral cavity)

The cornerstone of the cosmetic regulation is that cosmetics must be safe

[About the Cosmetic Regulation](#)

The key mechanisms to ensure cosmetic safety are the requirement to:

- Draw up a Cosmetic Product Safety Report
 - Part A, Cosmetic Product Safety Information
 - Part B, Cosmetic Product Safety Assessment
 - This must be carried out by a qualified safety assessor
- Notify each cosmetic product to a central EU Cosmetic Products Notification Portal (CPNP)
- Fragrances in cosmetics are an important part of the product. Information is required about fragrances to assist with the Safety Report and with product labelling.

[Cosmetics Europe – The Personal Care Association](#)



The label of a Cosmetic Product containing orange oil would require either the INCI name for orange oil (which depends on the type used), or the generic term 'parfum'.

The Cosmetic Product would require a safety assessment and notification in line with the regulation.

The label would also require the Limonene allergen to be declared on packaging if present at 10ppm or more in a leave on product, or 100ppm or more in a rinse off product.



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Detergents



The detergents regulation is focused on the protection of the environment and human health:

- Detergents are products containing soaps or other surfactants, intended for washing and cleaning processes, for example laundry detergent.

[The Detergents Regulation](#)

[UKCPI – The UK Cleaning Products Industry Association](#)

The key provisions of the detergents regulation are:

- Limitations based on the biodegradability of surfactants
- Requirements for testing of surfactants
- Labelling Requirements for consumer products,
 - This has implications for any fragrance in the product
- Requirement to provide Ingredient Datasheets for consumer products

[AISE – International Association for Soaps, Detergents and Maintenance Products](#)



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IFRA



IFRA is the International Fragrance Association, an industry association which publishes a set of standards for fragrance ingredient use .

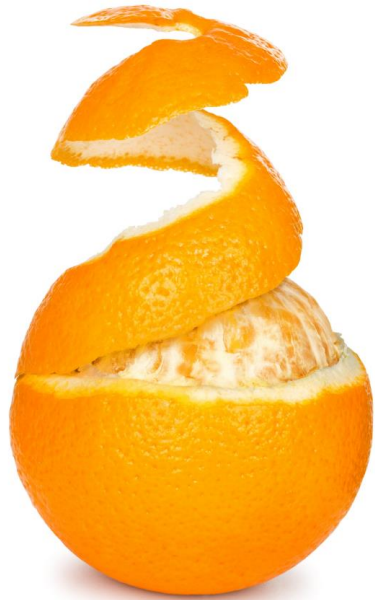
Key goals of the standards is to protect the health of fragrance consumers by:

- Limiting exposure to fragrance allergens
- Limiting exposure to ingredients with systemic toxicity or phototoxicity

IFRA publishes a code of practice and ingredient use limits which must be adhered to by all IFRA members.

[IFRA Global](#)





When using Orange oil in a fragranced product, the IFRA guidelines must be adhered to.

If the orange oil contains other IFRA limited components, e.g. Citral, those limits and recommendations must also be adhered to.

If the Orange Oil is a cold pressed oil bitter orange, containing furocoumarins, then the appropriate limits must be adhered to. This is to avoid phototoxic reactions.

The specification standard for Limonene is also relevant.



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Other Regulations



There are many other regulations which may be relevant for fragranced products, including the following which typically relate to finished products:

General Product Safety Directive

Businesses should only sell products which are safe, inform consumers of any risks associated with the products, ensure traceability to enable removal from the market in case of risk to consumers

[About the GPS Directive](#)

Toy Safety Directive

The safety criteria that toys must meet before they can be marketed in the EU

[About the Toy Directive](#)

The following rules typically relate to ingredients used in products:

CITES

The Convention on International Trade in Endangered Species of Wild Fauna and Flora

[About CITES](#)

EU ABS Regulation

Compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization

[About ABS](#)



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Example Ingredients



Limonene

- Limonene is found naturally in many essential oils, including orange oil
- Limonene is hazardous under CLP and the driver for the hazards associated with orange oil
- It's hazardous for transport, both for flammability and environmental reasons
- Limonene is labelled as an allergen on cosmetics
- Limonene is not IFRA limited, but there is a specification standard for limonene and essential oils containing high percentages of it
 - Should only be used when the level of peroxides is kept to the lowest practical level, for instance by adding antioxidants at the time of production



Methyl Eugenol

- Methyl eugenol is found naturally in Basil and Rose
- It's hazardous under CLP
- It's not hazardous for transport
- It is restricted in use by the cosmetic regulation
- It is IFRA limited due to systemic toxicity
 - The limits in the cosmetic regulation are half the limits in the IFRA Standards





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Example Formulations



Example Formulations

A fragranced reed diffuser could be hazardous for CLP, if so:

- Apply CLP label
- Pack according to CLP
- Supply SDS if requested by a workplace recipient (i.e. consumer product stored/used in industrial /professional setting)
- **It could be hazardous for transport, if so**
 - Transport labelling on outer packaging
- **Not a cosmetic or a detergent, so the cosmetic regulation and detergent regulation do not apply**
- **Could be IFRA limited**
 - Ensure IFRA limits are adhered to



Eau de Toilette or Body Spray

- **CLP Hazardous due to flammability, and potentially other hazards**
 - Supply a SDS if requested by a workplace (i.e. a consumer product stored/used in industrial /professional setting)
- **Hazardous for transport (flammable)**
 - Transport labelling on outer packaging
- **Comply with cosmetic regulation**
 - Safety assessment and PIF
 - Label / communicate appropriately
- **Could be IFRA limited**
 - Ensure IFRA limits are adhered to



About Formpak Software



Formpak ensures companies in the fragrance, cosmetics and air care sectors can create great products quickly, effectively and with the security that they meet regulatory standards.

We allow your creativity to flourish whilst simultaneously ensuring your products are fit for the market, whatever the size of your company. But Formpak offers much more beyond our software.

Our team's sector knowledge and expertise underpin all that we do and our customer support consistently receives positive feedback.



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