EUROPEAN UNION REGULATION: ESSENTIAL OILS AND RESINOIDS

GQSP GLOBAL QUALITY AND STANDARDS PROGRAMME

El futuro es de todos | Gobierno de Colombia

This publication is developed within the framework of the GQSP Colombia - Quality Program for the Chemical Chain in conjunction with ProColombia. The GQSP Colombia is executed by the United Nations Industrial Development Organization (UNIDO) and financed by the Secretary of State for Economic Affairs of the Swiss Confederation (SECO) and the Ministry of Commerce, Industry and Tourism through Colombia Productiva.

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1. Introduction

This technical sheet covers all products exported from Colombia to the European Union under HS code 3301: Essential oils (terpeneless or not), including concretes and absolutes; resinoids; extracted oleoresins; concentrates of essential oils in fats, in fixed oils, in waxes or the like, obtained by enfleurage or maceration; terpenic by products of the deterpenation of essential oils; aqueous distillates and aqueous solutions of essential oils.

This document will allow Colombian exporters to identify and understand the main requirements to export essential oils and resinoids from Colombia (exit requirements), as well as to access the European Union market (entry requirements). The different sections of the document cover all regulatory requirements and buyer requirements for this product group.

Please, note that it is the responsibly of each exporter to verify the regulations applicable to their product and their updates or modifications.

2. Colombian requirements: Exporting Essential Oils and Resinoids

Colombian exporters must meet a series of conditions before exporting essential oils and resinoids. Before engaging in the export process from Colombia, the exporter must always be registered at the DIAN[1] (Colombian Tax and Customs Department) adding in their RUT that they are going to export.

Essential oils and resinoids whose end-use is animal or veterinary have to obtain a zoo-sanitary certificate by the Colombian Agricultural Institute (ICA)[2] . For food or cosmetics industry end-use, the mandatory sanitary notification will be issued by the Colombian Food and Drugs Administration (Invima)[3] . For medical

1. https://www.dian.gov.co
2. https://www.ica.gov.co
3. https://www.invima.gov.co

or scientifically-controlled ends, the certificate is issued by the ICA or Invima.

In addition, exporters must have all the legal documentation applicable to their product.

3. International regulatory framework

3.1 Convention on International Trade in Endangered Species

The conservation and sustainable use of natural resources is a crucial issue in the international agenda, involving the public and private sectors, as well as civil society. The international market is subject to specific provisions which regulate the trade of threatened flora and fauna species, which are reflected in the European Union legislation.

Exports to the European Union of an endangered species, or its derivatives, need specific export permits issued by Colombia's competent authorities. The regulatory framework, its details and related procedures are explained below:

The Convention on International Trade in Endangered Species or CITES (Washington Convention)[4], is a multilateral treaty aimed at protecting endangered plants and animals. CITES went into force on 1 July 1975 and is directed at ensuring that international trade in wild animals and plants does not threaten the survival of at-risk species in the wild.

In CITES, plant (and animal) species are subject to different degrees of regulation according to three Appendices[5]:

- Appendix I includes species threatened by extinction, for which trade is subjected to stricter regulation, and is only authorised in exceptional circumstances for specimens of wild origin. Commercial trade in wild taken specimens of Appendix-I listed species is generally unallowed.

- Appendix II includes species that are not necessarily now threatened with extinction but may become so unless trade is strictly regulated.

- Appendix III contains species that are subject to regulation within the jurisdiction of a CITES Party and for which the co-operation of other CITES Parties is needed to prevent or restrict their exploitation.

4. https://cites.org/eng/disc/what.php
5. https://ec.europa.eu/environment/cites/pdf/referenceguide_en.pdf

CITES covers all parts of derivatives of plant species, unless specifically exempted, including extracts. Extracts are defined in CITES as any substance obtained directly from plant material by physical or chemical means regardless of the manufacturing process. An extract may be solid (e.g. crystals, resin, fine or coarse particles), semi-solid (e.g. gums, waxes) or liquid (e.g. solutions, tinctures, oil and essential oils)[6].

The implementation of CITES within the European Union is governed by a set of regulations known as EU Wildlife Trade Regulations:

Council Regulation (EC) No 338/97[7] (main regulation) on the protection of species of wild fauna and flora by regulating trade therein.

- Commission Regulation (EC) No 865/2006[8] (as amended by Commission Regulation (EC) No 100/2008, Commission Regulation (EU) No 791/2012 and Commission Implementing Regulation (EU) No 792/2012) laying down detailed rules concerning the implementation of Council Regulation (EC) No 338/97.
- Commission Implementing Regulation (EU) No 792/20129 of 23 August 2012 laying down rules for the design of permits, certificates and other documents provided for in Council Regulation (EC) No 338/97 on the protection of species of wild fauna and flora by regulating the trade thereinand amending Regulation (EC) No 865/2006.

These regulations are directly applicable in the Member States[10] and go beyond CITES-listed species. The main differences between CITES and the EU Regulation are highlighted in the document *The Differences between EU and CITES Provisions in a Nutshell*[11].

The species covered by Regulation (EC) No 338/97 are listed in four Annexes (A to D)[12]:

Annex A:

- All CITES Appendix I species, except where EU Member States have entered a reservation
- Some CITES Appendix II and III species, for which the EU has adopted stricter domestic measures.
- Some non-CITES species.

6. https://cites.org/eng/app/appendices.php
7. https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1583168086765&uri=CELEX:01997R0338-20200101
8. https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1484753534360&uri=CELEX:02006R0865-20190227
9. https://eur-lex.europa.eu/search.html?DTN=0792&DTA=2012&qid=1484753629149&DB_TYPE_OF_ACT=regulation&DTS_DOM=EU_LAW&typeOfActStatus=REGULATION&type=advanced&lang=en&SUBDOM_INIT=CONSLEG&DTS_SUBDOM=CONSLEG
10. https://ec.europa.eu/environment/cites/pdf/referenceguide_en.pdf
11. https://ec.europa.eu/environment/cites/pdf/differences_b_eu_and_cites.pdf
12. https://ec.europa.eu/environment/cites/legislation_en.htm

Annex B:

- All other CITES Appendix II species, except where EU Member States have entered a reservation.
- Some CITES Appendix III species.
- Some non-CITES species.

Annex C:

- All other CITES Appendix III species, except where EU Member States have entered a reservation.

notifications according to the specific Annex in which they're listed. **An export permit from the supplying country (Colombia) is also required for species listed in Appendices I and II of CITES (Annexes A and B of the EU regulation), and for Appendix III (Annexes C and D) if the supplying country's government has listed the species in this appendix**[13]

Examples of oil-bearing plants in each Annex of Regulation (EC) Nº 338/97:

Annex	Oil-bearing plant species examples
Annex A	• Brazilian rosewood (Dalbergia nigra) • Guatemalan fir (Abies guatemalensis)
Annex B	• Red sandalwood (Pterocarpus santalinus) • African rosewood, Senegalese rosewood, kosso (Pterocarpus erinaceus) • Jatamansi (Nardostachys grandiflora)
Annex C	• Magnolia liliifera var. obovata (*Nepal*)
Annex D	• Rose of Jericho (*Selaginella lepidophylla*)

Annex D:

- Some CITES Appendix III species for which the EU holds a reservation.
- Some non-CITES species in order to be consistent with other EU regulations on the protection of native species, such as the Habitats Directive and the Birds Directive.

In order for buyers in the European Union to import species (and derivatives) that are listed in the Annexes, they must arrange permits / notifications according to the specific Annex in which they're listed. **An export permit from the supplying country (Colombia) is also required for species listed in Appendices I and II of CITES (Annexes A and B of the EU regulation), and for Appendix III (Annexes C and D) if the supplying country's government has listed the species in this appendix**[13]

The import permit is only issued after a copy of a valid export permit from the CITES Authority in the country of export has been received by the competent authority in the EU country.

Exporters in Colombia must begin the export procedure by contacting the Colombian CITES Management Authorities[14], and apply for a CITES export/re-export permit. The permits (import and export or re-export) shall be presented, as originals, to the Customs.

13. https://www.mite.gov.it/sites/default/files/archivio/allegati/cites/cites_reference_guide_december_2020_final.pdf
14. https://cites.org/eng/parties/country-profiles/co/national-authorities

Export permits must be endorsed, with quantity, signature and stamp, by the competent authority, in the export endorsement block of the document. If the export document has not been endorsed at the time of export, the Management Authority of the importing country in the European Union should liaise with the Colombian authorities to determine the acceptability of the document[15].

More information can be found on the page of the European Commission: *CITES: Permits, Certificates and Notifications*[16].

3.2 Nagoya Protocol

The implementation of the Nagoya Protocol on Access and Benefit Sharing (ABS) has important implications for natural ingredients, including essential oils and resinoids, and their suppliers. Even though the responsibility to comply with the European regulation belongs to the user of the generic resource (i.e. European importer, manufacturer, etc.) Colombian exporters of natural ingredients must understand and comply with the local Access and Benefit Sharing legislation and assist their buyers in achieving compliance. This can be done by developing specific checkpoints and monitoring obligations through the supply chain.

The Nagoya Protocol, on Access and Benefit Sharing (ABS), is an international treaty which has been in force since 2014. Its main objective is the fair and equitable sharing of benefits derived from the use of genetic resources. This means that, when benefits arise from research or development on genetic resources (including when it leads to the commercial use of a developed product), these benefits should be shared fairly and equitably with the country providing these resources[17].

The provisions of the protocol offer legal protection and transparency to both providers and users of genetic resources. Furthermore, they help ensure benefit-sharing, particularly when genetic resources leave the country of origin, and establish more predictable conditions for access to genetic resources.

The European Union is a signatory of the Nagoya Protocol. This means that the European Union as a regional bloc and their individual countries are legally obliged to implement mechanisms and to comply with its principles. These obligations are reflected in business practices in both export and import countries / end markets. As such, Colombian exporters are also expected to comply with the national legislation addressing Access and Benefit Sharing (ABS).

15. https://www.mite.gov.it/sites/default/files/archivio/allegati/cites/cites_reference_guide_december_2020_final.pdf
16. https://ec.europa.eu/environment/cites/info_permits_en.htm
17. https://ec.europa.eu/environment/nature/biodiversity/international/abs/index_en.htm

The Nagoya Protocol is implemented in the European Union through Regulation (EU) No 511/2014 of the European Parliament and of the Council, on 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 in the Union[18].

The regulation holds users of genetic resources or traditional knowledge accountable for exercising and demonstrating due diligence in relation to access to these resources / knowledge. The due diligence process includes compliance with the applicable legislation in countries where the genetic resource is sourced (example: Colombia) in terms of:

- Obtaining prior informed consent (PIC) of the country in which the genetic resource is located before accessing the resource.

- Negotiating and agreeing on the terms and conditions of access and use of this resource through the establishment of mutually agreed terms (MAT).

This due diligence process also implies that users should collect, keep and transfer to subsequent users the information relevant to ensure compliance with the due diligence requirements. Users also have the obligation to declare to the National Competent Authorities of their Member State that they exercised due diligence, at the end of utilization. This declaration is called Due Diligence Declaration (DDD)[19].

The European Commission has published the *Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the 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 in the Union*[20] (Horizontal Guidance) with the purpose to help users to comply with the requirements of Regulations (EC) 511/2014 and (EC) 2015/1866. The regulations apply to derivatives such as essential oils and resinoids. According to the EC Horizontal Guidance, “access to derivatives is covered when it also includes genetic resources for utilization, i.e. when access to a derivative is combined with access to a genetic resource from which that derivative was or is obtained.”[21]

18. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0511
19. https://ifrafragrance.org/docs/default-source/guidelines/nagoya-protocol-guidance/il1090-09-04-2020-ifra-iofi-guidance-document-on-nagoya-protocol-and-abs-regulations-(att-03)-european-union-(april-9-2020).pdf?sfvrsn=50a72c37_6
20. https://op.europa.eu/en/publication-detail/-/publication/aefa4237-5477-11eb-b59f-01aa75ed71a1/language-en
21. https://ifrafragrance.org/docs/default-source/guidelines/nagoya-protocol-guidance/il1090-09-04-2020-ifra-iofi-guidance-document-on-nagoya-protocol-and-abs-regulations-(att-03)-european-union-(april-9-2020).pdf?sfvrsn=50a72c37_6

4. EU: Chemicals legislation

4.1 Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), Regulation (EC) No 1907/2006 of the European Parliament and of the Council[22], is a regulation of the European Union which was adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry[23]. This regulation requires the industry to have sufficient knowledge about the properties of their substances and to manage their potential risks.

One of the main reasons for developing and adopting the REACH Regulation was that a large number of substances have been manufactured and placed on the market in Europe for several years with insufficient information on the hazards that they pose to human health and the environment[24].

A "substance" is defined in REACH[25] [26], as: a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition[27].

REACH has consequences mainly to Natural Complex Substances (NCS) of botanical origin used in cosmetics. The NCS are described by ISO 9235:20138 (Aromatic Natural Raw Materials), which include essential oils, oleoresins and resinoids[28].

The registration and authorization requirements of REACH do not apply to substances traded in quantities lower than one tonne by one specific company, or used in[29]:

- Scientific research and development
- Food and feed
- Medicinal products

European Union-based manufacturers or importers are the ones responsible for compliance with the REACH regulation. However, non-EU suppliers are expected to facilitate the necessary information and

22. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20140410
23. https://echa.europa.eu/regulations/reach/understanding-reach
24. https://ec.europa.eu/environment/chemicals/reach/reach_en.htm
25. https://eur-lex.europa.eu/legal-content/ES/TXT/PDF/?uri=CELEX:32006R1907&from=EN
26. https://ec.europa.eu/environment/chemicals/reach/reach_en.htm
27. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20140410
28. https://echa.europa.eu/documents/10162/13643/efeo_ifra_guidelines_es.pdf/c85bc8c4-f71a-48ac-8b94-607be5cc4950
29. https://echa.europa.eu/support/getting-started/am-i-exempt

documentation which will enable EU importers to comply with their regulatory obligations. Alternatively, a non-EU supplier of essential oils and resinoids can register ingredients themselves through an "only representative" established in the EU[30]. This can give them more flexibility as a supplier, as they are not dependent on an importer who is registered[31]. However, it is important to keep in mind that REACH costs and fees are very high, and the process requires extensive documentation.[32]

The website of the European Chemicals Agency (ECHA) *Understanding REACH*[33] explains in detail the process of Identification, Registration, Evaluation and Authorization / Restriction of substances. In addition, the website *Information on Chemicals*[34] contains the full list of substances which are:

- Registered before the European Chemicals Agency (ECHA), for which all public data submitted to ECHA in REACH registration dossiers by substance manufacturers, importers, or their representatives, as laid out by the REACH Regulation, are available[35]. Examples:
  - Citral: CAS number: 5392-40-5; EC number 226-394-6[36]
  - Menthol: CAS number 89-78-1; EC number 201-939-0[37]
  - Carvacrol: CAS number: 499-75-2; EC number 207-889-6[38]
  - Carvacrol-rich essential oil obtained from the leaves of Origanum spp., Labiatae, by distillation: CAS number -; EC number 947-697-6[39]
  - Thymol: CAS number: 89-83-8; EC number 201-944-8[40]
  - Thyme, Thymus vulgaris, ext.: CAS number 84929-51-1; EC number 284-535-7[41]

- Pre-registered. Pre-registration intentions for these substances were submitted to the European Chemicals Agency (ECHA) between 1 June and 1 December 2018. Full registration is required for all substances manufactured or imported in quantities of one tonne or more per year per manufacturer or importer, unless they are exempted[42]. Examples:
  - *Uvaria cananga*, ext.: CAS number 93062-98-7; EC number 296-855-4[43]

30. https://echa.europa.eu/regulations/reach/registration
31. https://www.cbi.eu/market-information/natural-ingredients-cosmetics/buyer-requirements
32. http://www.cirs-reach.com/REACH/REACH_Registration_Fees.html
33. https://echa.europa.eu/regulations/reach/understanding-reach
34. https://echa.europa.eu/information-on-chemicals
35. https://echa.europa.eu/information-on-chemicals/registered-substances
36. https://echa.europa.eu/substance-information/-/substanceinfo/100.023.994
37. https://echa.europa.eu/substance-information/-/substanceinfo/100.001.763
38. https://echa.europa.eu/substance-information/-/substanceinfo/100.007.173
39. https://echa.europa.eu/substance-information/-/substanceinfo/100.259.860
40. https://echa.europa.eu/substance-information/-/substanceinfo/100.001.768
41. https://echa.europa.eu/substance-information/-/substanceinfo/100.076.823
42. https://www.chemsafetypro.com/Topics/EU/REACH_Registration.html
43. https://echa.europa.eu/substance-information/-/substanceinfo/100.088.010

- *Physalis physalis*, ext.: CAS number 93062-84-1; EC number 296-840-2[44]
- *Lippia dulcis*, ext.: CAS number 90063-57-3; EC number 290-016-6[45]
- *Eclipta alba*, ext.: CAS number 93165-22-1; EC number 296-907-6[46]
- *Aloysia triphylla*, ext.: CAS number 85116-63-8; EC number 285-515-0[47]

- Registered in quantities between 1 and 10 tonnes, predicted to meet criteria for category 1A or 1B for carcinogenicity, mutagenicity or reproductive toxicity (defined in Annex III of REACH)[48]. The fact that a substance is not in this list does not necessarily mean that the criteria for Annex III are not met[49]. If the substance is in the Annex III inventory, the company responsible for its registration will most likely need to submit the full Annex VII information[50]. Examples:
  - *Cinnamomum cassia*, ext.: CAS number 8007-80-5; EC number 616-916-4. Criteria: Suspected mutagen, Suspected skin sensitizer[51].
  - *Coffe, Coffea arabica*, ext.: CAS number 84650-00-0; EC number 283-481-1. Criteria: Suspected toxic for reproduction[52].

4.2 Classification, Labelling and Packaging (CLP)

The Globally Harmonized System (GHS) of Classification and Labelling of Chemicals[53] is a system developed at the United Nations level to standardize and harmonize the management of chemicals globally. The United Nations Purple Book[54] is a guide on the implementation of the GHS which:

- Defines the physical, human health and environmental hazards and harmonizes the criteria for their classification according to these hazards;

- Standardizes the content and format of the chemical substances' labelling and Safety Data Sheets (SDS).

The GHS is governed in the European Union through Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging

44. https://echa.europa.eu/substance-information/-/substanceinfo/100.087.996
45. https://echa.europa.eu/substance-information/-/substanceinfo/100.081.802
46. https://echa.europa.eu/substance-information/-/substanceinfo/100.088.057
47. https://echa.europa.eu/substance-information/-/substanceinfo/100.077.713
48. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1907&qid=1555077068696&from=EN#page=295
49. https://echa.europa.eu/information-on-chemicals/annex-iii-inventory
50. https://echa.europa.eu/support/registration/what-information-you-need/information-requirements-100-tn
51. https://echa.europa.eu/information-on-chemicals/annex-iii-inventory/-/dislist/details/AIII-100.132.785
52. https://echa.europa.eu/information-on-chemicals/annex-iii-inventory/-/dislist/details/AIII-100.075.866
53. https://unece.org/about-ghs
54. https://unece.org/ghs-rev8-2019

of substances and mixtures[55]. **The regulation on Classification and Labelling of Chemicals (CLP) applies to essential oils and resinoids regardless of the quantities traded. Therefore, substances traded in quantities of less than one tonne are not exempted.**

Classification and labelling

Regulation (EC) No 1272/2008 defines the content and presentation of the label. The label must be firmly attached to one or more of the packaging's surfaces and has to include the following information (as per Article 17):

- The name, address and telephone number of the supplier.
- The nominal quantity of a substance or mixture in packages made available to the general public, unless this quantity is specified elsewhere on the package (if applicable).
- Product identifiers (example: EC number, CAS number).
- Where applicable (i.e. for hazardous substances), hazard pictograms, signal words, hazard statements, precautionary statements and supplemental information required by other legislation[56].

Article 17 of Regulation (EC) No 1272/2008 also establishes that the label shall be written in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

Articles 31 to 33 of the Regulation (EC) No 1272/2008 addresses the rules governing the applicable of labels:

- Labels shall be readable horizontally when the package is set down normally.
- The colour and presentation of any label shall be such that the hazard pictogram stands out clearly.
- The label elements shall be clearly and permanently marked. They shall stand out clearly from the background and be of such size and spacing as to be easily read.
- The shape, colour and the size of a hazard pictogram as well as the dimensions of the label shall be as set out in section 1.2.1 of Annex I.
    - Hazard pictograms shall have a black symbol on a white background with a red frame sufficiently wide to be clearly visible.

55. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008R1272
56. https://echa.europa.eu/es/regulations/clp/labelling

- Hazard pictograms shall be in the shape of a square set at a point. Each hazard pictogram shall cover at least one fifteenth of the surface area of the harmonized label but the minimum area shall not be less than 1 cm^2.

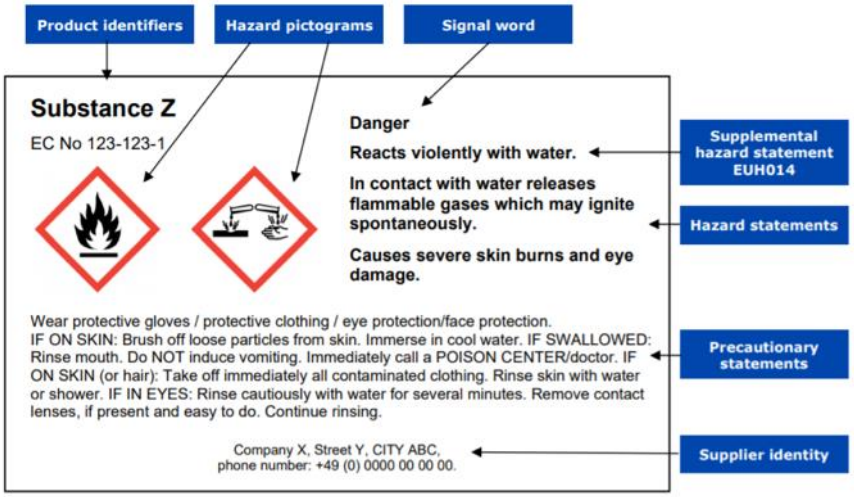
- The dimensions of the label shall be as follows:

Capacity of the package	Dimensions of the label, in milimeters
Not exceeding 3 liters:	If posible, at least 52 x 74
Greater than 3 liters but, not exceeding 50 liters:	At least 74 x 105
Greater than 50 liters but not exceeding 500 liters:	At least 105 x 148
Greater than 500 liters:	At least 148 x 210

- The hazard pictograms, word of caution / signal word, hazard statements and precautionary statements shall be located together on the label.

The European Chemicals Agency (ECHA) has a detailed document, the *Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008*[57], provides step-by-step instructions on how to comply with this regulation. It also contains a few examples of generic labels complying with the CLP requirements, such as:

57. https://echa.europa.eu/documents/10162/23036412/clp_labelling_en.pdf/89628d94-573a-4024-86cc-0b4052a74d65



(a) inner packaging for supply

(b) outer packaging for supply

(c) transport packaging

Source: Guidance on labelling and packaging in accordance with Regulation (EC) Nº 1272/2008.
Version 4.2. March 2021

You can find an elaborate definition of the flammability, risk phrases and safety phrases in Directive 2001/59/EC[58]. The Directive provides technical information for implementing European Union regulation on Classification, Labelling and Packaging. In addition, the database of the *C&L Inventory*[59] on the website of the European Chemicals Agency (ECHA) contains all the necessary information on the classification and labelling of the substances which have been notified and registered by manufacturers and importers in the EU. Examples:

Hazard class and Category code(s) / Hazard statement code(s)	Labelling phrase	Signal words and Pictograms
Cardamon Exxential Oil: EC number 943-157-9[60]		
Flam. Liq. 3 / H226 Asp. Tox. 1 / H304 Skin Irrit. 2 / H315 Skin Sens. 1 / H317 Eye Irrit. 2 / H319 Aquatic Chronic 2 / H411	Flammable liquid and vapour. May be fatal if swallowed and enters airways. Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation. Toxic to aquatic life with long lasting effects.	Signal Word: Danger Pictograms: 
HE Verbena triphyllia: EC number 676-658-3[61]		
Asp. Tox. 1 / H304 Skin Irrit. 2 / H315 Skin Sens. 1 / H317 Aquatic Chronic 2 / H412	May be fatal if swallowed and enters airways Causes skin irritation. May cause an allergic skin reaction. Harmful to aquatic life with long lasting effects.	Signal Word: Warning Pictograms: 

The classification and labelling information for specific substances must also be included in the Safety Data Sheets (SDS), regulated in the European Union by Annex II of the REACH regulation[62], which contains the necessary data that an SDS must have. This is a separate document that must be submitted to the buyer, and which is explained in more detail in section **7.2. Documentation requirements.**

58. https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:225:0001:0333:EN:PDF
59. https://echa.europa.eu/es/information-on-chemicals/cl-inventory-database
60. https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/250174
61. https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/notification-details/206786/922705
62. https://echa.europa.eu/regulations/reach/legislation

Packaging

Article 35 of Regulation (EC) No 1272/2008 defines the packaging requirements of hazardous substances[63]:

- The packaging is designed, constructed and fastened so that the contents cannot escape.
- The materials of the packaging and fastening are not damaged by the contents and are not liable to form hazardous compounds with the contents.
- The packaging and fastenings are strong and solid throughout to ensure that they will not loosen.
- Packaging fitted with replaceable fastening devices is properly designed to allow repeated refastening without the contents escaping.
- The packaging does not attract or arouse the curiosity of children or mislead the consumer when supplied to the general public.
- The packaging does not have a similar presentation or a design used for foodstuff or animal feed stuff or medicinal or cosmetic products which would mislead the consumers.

For recommendations of specific packaging materials which will allow suppliers of essential oils and resinoids to comply with these requirements, consult section **7.3. Packaging and Transport.**

5. EU: Cosmetics legislation

In the European Union, cosmetic products are regulated by Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products[64]. The regulation requires the responsible person to safeguard that the cosmetic product has gone through a basic safety assessment based on relevant technical information before the product can be marketed in the European Union. In addition, a product safety report has to be prepared according to Annex I of this regulation. The guidelines for Annex I are set out in Commission Implementing Decision 2013/674 / EU[65].

The cosmetics regulation mainly focuses on finished cosmetics products, but has consequences for suppliers of natural ingredients such as essential oils and resinoids, particularly. Annexes II and III establish that the responsible individual or company in the European Union (importer, agent, manufacturer, etc.) must safeguard compliance to the legal requirements. However, this

63. https://echa.europa.eu/documents/10162/23036412/clp_labelling_en.pdf/89628d94-573a-4024-86cc-0b4052a74d6
64. https://ec.europa.eu/growth/sectors/cosmetics/legislation_en
65. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013D0674

means that non-EU ingredient suppliers have the direct responsibility to support the responsible person or company in complying with its various provisions, as detailed in the next sections.[66]

CosIng database

CosIng is the European Commission database for information on cosmetic substances and ingredients contained in the:

- Cosmetics Regulation (EC) No 1223/2009 of the European Parliament and of the Council[67]
- Cosmetics Directive 76/768/EEC (cosmetics directive), as amended[68]
- Glossary of common ingredient names for the purpose of labelling cosmetic products placed on the market (as established by Decision (EU) 2019/701 of 5 April 2019)[69]

The Cosmetic Ingredient (CosIng) database[70] has two sections:

- Section 1 - It consists of all the cosmetic ingredients, except perfume and aromatic raw material.
- Section 2 - It consists cosmetic ingredients related to perfume and aromatic raw material.

The CosIng database contains information on the ingredient's identity, notably identifiers such as INCI name, Ph. Eur., INN, IUPAC, and their chemical names; its registration numbers according to EINECS/ELINCS, CAS; its function(s) in cosmetics and all mandatory restrictions, conditions of use and warnings.

The database does not constitute a list of ingredients necessarily authorized for use in cosmetic products, although they have been assigned with an INCI name (International Nomenclature Cosmetic Ingredient)[71]. The qualification of a product is to be decided by the national competent authorities, under the supervision of the courts, on a case-by-case basis, taking into account all the characteristics of the product. In addition, the use of any ingredient in cosmetic products must be supported by a safety assessment of the product.[72]

If an ingredient is not registered in CosIng, it may still be listed in the cosmetic product using its INCI name.

66. https://www.aemps.gob.es/publicaciones/publica/docs/Guia_Aceites_Esenciales.pdf?x42633
67. https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32009R1223
68. https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A31976L0768
69. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019D0701&from=EN
70. https://ec.europa.eu/growth/sectors/cosmetics/cosing_en
71. https://ec.europa.eu/growth/tools-databases/cosing/layout/CosIng_Manual.pdf
72. https://ec.europa.eu/growth/sectors/cosmetics/cosing_es

5.1 Cosmetic Products Regulation, Annex II – Prohibited Substances

Annex II of Regulation (EC) No 1223/2009 contains substances which are banned from use in any cosmetic products marketed for sale or use in the European Union. Among the 2.400+ substances listed in this annex[73], there are those which relate to essential oils and resinoids. Examples:

- Substances that are prohibited in cosmetic products, regardless of their function. Examples:
  - *Juniperus sabina L.* (leaves, essential oil and galenical preparations): CAS number 90046-04-1; EC number 289-971-1[74].
  - *Pilocarpus jaborandi Holmes* and its galenical preparations: CAS number 84696-42-4; EC number 283-649-4[75]
- Substances that are prohibited in cosmetic products for a specific function. Example:
  - Peru Balsam (INCI name: Myroxylon pereirae): CAS number 8007-00-9; EC number 232-352-8, prohibited for use as a fragrance ingredient[76].
  - Verbena essential oils and derivatives, other than absolutes: CAS number 8024-12-2; EC number 285-515-0, prohibited for use as a fragrance ingredient[77].
- Substances that are prohibited in cosmetics products except for normal content in natural essences and subject to the maximum concentration limits and other conditions. Examples:
  - Safrole (5-Allyl-1,3-benzodioxole): CAS number 94-59-7 / EC number 202-345-4, except for normal content in the natural essences used and provided that the concentration does not exceed: 100 ppm in the finished cosmetic product, 50 ppm in products for dental and oral hygiene, and provided that Safrole is not present in toothpastes intended specifically for children[78].

The complete list of prohibited substances can be found in Annex II, and its updates are available on the platform of the *European Chemicals Agency: Cosmetic Products Regulation, Annex II - Prohibited Substances*[79].

73. https://www.aemps.gob.es/publicaciones/publica/docs/Guia_Aceites_Esenciales.pdf?x54046
74. https://echa.europa.eu/substance-information/-/substanceinfo/100.081.761
75. https://echa.europa.eu/substance-information/-/substanceinfo/100.076.017
76. https://echa.europa.eu/substance-information/-/substanceinfo/100.029.409
77. https://echa.europa.eu/legislation-obligation/-/obligations/100.077.713
78. https://www.echa.europa.eu/web/guest/substance-information/-/substanceinfo/100.002.133
79. https://www.echa.europa.eu/cosmetics-prohibited-substances

5.2 Cosmetic Products Regulation, Annex III - Restricted Substances

Annex III of Regulation (EC) No. 1223/2009 lists substances whose use in cosmetic products in the European Union is banned, except under certain conditions; i.e. field of application or use, maximum allowable concentration limits in finished products, and any additional limitations.

Annex III contains 26 substances known as fragrance allergens, subject to mandatory labelling conditions due to their allergenic potential. Their presence in cosmetic products must be mentioned on the packaging when their concentration exceeds the threshold of 10 ppm (0.001%) in leave-on products and 100 ppm (0.01%) in rinse-off products[80].

These substances are listed in a document drafted by the European Commission's Scientific Committee on Consumer Safety[81]: Alpha-isomethyl Ionone, Amyl Cinnamal, Amyl Cinnamyl Alcohol, Anise Alcohol, Benzyl Alcohol, Benzyl Benzoate, Benzyl Cinnamate, Benzyl Salicylate, Butylphenyl Methylpropional, Cinnamal, Cinnamyl Alcohol, Citral, Citronellol, Coumarin, Eugenol, Evernia Prunastri Extract, Evernia Furfuracea Extract, Farnesol, Geraniol, Hexyl Cinnamal, Hydroxycitronellal, Hydroxyisohexyl 3-cyclohexene Carboxaldehyde (HICC), Isoeugenol, Limonene, Linalool, Methyl 2-octynoate.

Other examples of restricted substances are:

- Verbena absolute (Lippia citriodora Kunth.): CAS number 8024-12-2, with a maximum concentration of 0.2% in all cosmetic products[82].

- *Picea mariana* oil and extract: CAS number 91722-19-9; EC number 294-420-3. Restriction: Peroxide value less than 10 mmoles/L (This limit applies to the substance and not to the finished cosmetic product)[83].

The complete list of substances whose use in cosmetic products in the European Union is banned, except under certain conditions of Annex III and its updates are available on the platform of the *European Chemicals Agency: Cosmetic Products Regulation, Annex III - Restricted Substances*[84].

5.3 Cosmetic Products Regulation, Annex IV – Allowed Colorants

80. https://www.edqm.eu/en/guidance-essential-oils-cosmetic-products
81. https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_073.pdf
82. https://echa.europa.eu/legislation-obligation/-/obligations/100.077.713
83. https://www.echa.europa.eu/web/guest/legislation-obligation/-/obligations/100.085.801
84. https://echa.europa.eu/cosmetics-restricted-substances

Not relevant for essential oils and resinoids.

5.4 Cosmetic Products Regulation, Annex V – Allowed Preservatives

Not relevant for essential oils and resinoids.

5.5 Cosmetic Products Regulation, Annex VI – Allowed UV Filters

Not relevant for essential oils and resinoids.

6. Industry standards

6.1 IFRA Standards for fragrance ingredients

The sub-sector of fragrances has specific standards concerning the use of substances in fragrance products. The standards of the sector association, the *International Fragrance Association* (IFRA)[85], establish specifications for several essential oils regarding the maximum content of their constituents. These standards set out rules for the use of various fragrance materials based on scientific assessments. These rules include:

- Prohibition: a ban on the use of a material
- Restriction: rules on the maximum quantity to be used and/or the products in which certain materials can be use
- Specification: other conditions on the type of material (such as purity criteria)[86].

In case a product contains the constituents mentioned in the inventory of *IFRA Standards Library*[87], the fragrance manufacturer must present a Certificate of Conformity to the IFRA standards (***IFRA Statement***) according to the format of the following document: *Template for Certificate of Conformity to the IFRA Standards (DOC)*[88]. To fill in this document, the fragrance manufacturer may request their supplier to submit an IFRA Statement for the specific ingredient they supply. This will require the supplier to know the ingredient's constituents in detail. IFRA's inventory has specific information about each constituent, and the different *Natural Complex Substances* (NCS) that it contains. Example: Geraniol[89] (page 2).

The Certificate of Conformity is a document which is agreed upon

85. http://www.ifraorg.org
86. https://ifrafragrance.org/safe-use/standards-101-new
87. https://ifrafragrance.org/safe-use/library
88. https://ifrafragrance.org/safe-use/standards-documentation
89. https://ifrafragrance.org/pdf/web/viewer.html?file=/standards/IFRA_STD_037.pdf

between the ingredient / mixture manufacturer and their client (formulator, manufacturer of finished products, etc.). The compilation of this document is based on a trust commercial relationship between them; IFRA is not involved in its preparation and takes on no responsibility with respect to the content or format of any such Certificate of Conformity[90].

6.2 Other standards

ISO standards

The physical, organoleptic, chemical and chromatographic characteristics of essential oils are set globally through various ISO standards[91]. The subjects covered by these standards range from nomenclature, sampling and analysis to specific quality standards of specific essential oils such as Essential oil of oregano [Origanum vulgare L. subsp. hirtum (Link) letsw], Essential oil of cypress (Cupressus sempervirens L.), etc. The compliance to these ISO standards as a market requirement varies across buyers in the European Union. Some buyers may require specific standards due to their quality control system or certifications (for example, compliance to ISO 9235 [Aromatic natural raw materials] is a minimum requirement for essential oils used in Natrue-certified natural cosmetics[92]), but it's a case-by-case subject than a general market requirement.

COSMOS

The COSMOS standard covers all aspects of the sourcing, manufacturing, marketing and control of cosmetic products. Products that are COSMOS certified must be formulated using only ingredients that the standard allows. Raw materials must be certified or approved: Certified ingredients are organic, while approved raw materials are not organic[93]. The complete list of COSMOS-certified cosmetic products can be found in the database: *COSMOS-certified cosmetic products*[94].

NaTrue

NaTrue is also a certification that experiences growth in the European cosmetics market, although not as widely as COSMOS, but equally applicable to both ingredients and finished cosmetics. The different certification steps are described on the NaTrue website and with documents available in Spanish[95]. The standards include elements such as: prohibition of animal testing, organic production and labeling, prohibition of the use of

90. https://ifrafragrance.org/docs/default-source/ifra-code-of-practice-and-standards/49th-amendment/ifra-49th-amendment-(att-01)---guidance-for-the-use-of-ifra-standardsa7006c445f36499bbb0eb141e8c0d4be.pdf?sfvrsn=7fb244c8_2
91. https://www.iso.org/committee/48956/x/catalogue/
92. https://www.natrue.org/uploads/2019/06/EN-NATRUE-Label_Requirements_V3_8-1-1.pdf
93. https://www.cbi.eu/market-information/natural-ingredients-cosmetics/how-prepare-technical-dossier-cosmetic-ingredient
94. http://cosmos-standard-rm.org/data/indexcp.php
95. https://natrue.org/uploads/2019/05/ES-NATRUE-Label_Requirements_V3.8-1.pdf

Genetically Modified Organisms (GMOs), use of aromatic natural raw materials according to the ISO 9235 standard, respect to biodiversity, etc.

7. Quality and safety requirements

7.1 Environment, Health and Safety

Prior to starting a commercial relationship with a new supplier of ingredients, buyers in the European Union normally implement a supplier questionnaire to assess their Standard Operating Procedures (SOPs) regarding environment, health and safety – as well as general quality management in the manufacture of ingredients. This assessment is carried out differently by each company and it is part of an internal process. It is also part of a trust-building process between buyer and supplier. The supplier questionnaires may include subjects such as:

- Information about the company: year of foundation, address, contact information, location of the manufacturing site, type of company, main activities.
- Process of raw material sourcing and approval of suppliers.
- Implementation of Good Agricultural Practices.
- Production capacity.
- Company's organigram.
- Experience / track record in international markets.
- ISO 9001 or the implementation of equivalent processes.
- Format and frequency of internal audits.
- Tools and instruments for quality management.
- Customer management processes.
- Processes of compliance with the regulatory framework of international markets.
- Capacity to comply with documentation obligations, such as technical data sheets, certificates of analysis and safety data sheets.
- Capacity to comply with REACH regulation.
- Processes of testing and verification of products to ensure compliance with applicable regulatory requirements and performance standards.
- Processes of verification, maintenance and calibration of machinery.
- Existence of an *in-situ* laboratory and its accreditations.
- Control processes related to: allergens, contaminants, foreign materials, stock segregation, packaging and shipping of products.
- Cleaning schedules for: warehouse, manufacturing plant, packaging area.
- Recall processes and contingency plans.
- Implementation of health and safety policies.
- Implementation of a system based on the principles of hazard analysis and critical control points (HACCP) + HACCP flow chart.

- Implementation of other systems for quality and safety management: ISO22000 / FSSC22000, IFS, BRC, etc. / Good Manufacturing Practices (GMP); ISO 22716 (Cosmetics – Good Manufacturing).
- Procedure for reporting of accidents on site.
- Fire safety plan.
- Personal Protective Equipment (PPE) plan.
- Pest control plan.
- Implementation of organic certification.
- Registration in sustainability platforms such as SEDEX, etc.
- Implementation of a corporate social responsibility policy or code of conduct, supported by certifications such as SA8000.
- Certifications such as fair trade (Fairtrade, Fair for Life), and other: FairWild, UEBT, etc.
- Employee training programs.
- Certifications for environmental management such as ISO14000.
- Implementation of internal environmental policies.

The **Workbook for preparing a technical dossier for cosmetic ingredients: vegetable oils, essential oils and botanical extracts**[96], compiled by Andrew Jones (Fair Venture Consulting)[97] and ProFound – Advisers In Development[98] for the Dutch Center for the Promotion of Imports from Developing Countries (CBI)[99] has a few examples of questions from supplier questionnaires that are implemented by European buyers. For instance:

Do you have a documented Quality Management System? If yes, how often is it reviewed? *Please include a copy of the index page or Standard Operating Procedure (SOP) and outline content of SOP*
How do you approve your raw material suppliers? *If referring to a SOP, please provide a copy or outline of content of SOP*
Do you have formal risk assessments such as HACCP systems in place? *Please also provide a flowchart*

Raw material production

Buyers in the European Union may expect their suppliers of essential oils and resinoids to guarantee that the botanical raw material used in the manufacturing of these ingredients comply with Good Agricultural Practices (GAP), based on the principles of risk analysis and prevention, Integrated Pest Management (IPM) and Integrated Crop Management (ICM). Some essential oil buyers will also expect suppliers to comply with the World Health Organization's guidelines on Good Agricultural and Collection Practices (GACP) for medicinal

96. https://www.cbi.eu/market-information/natural-ingredients-cosmetics/how-prepare-technical-dossier-cosmetic-ingredient
97. https://www.fairventure.com
98. https://thisisprofound.com
99. https://www.cbi.eu

plants[100], but usually only required by more technical products and directed to the health market.

There is also an interesting growth among European buyers in the demand for organic-certified essential oils and resinoids, which requires compliance with Regulation (EU) No 2018/848 of the European Parliament and of the Council on organic production and labelling of organic products. Organic certification is often perceived as a guarantee of product safety, since it lowers the risks of cross-contamination by pesticides and other impurities.

Manufacturing

At the manufacturing level, buyers of essential oils and resinoids in the European Union expect suppliers to implement a system based on Hazard Analysis and Critical Control Points (HACCP). This is a minimum requirement for food ingredients (example: flavourings), but it is also commonly applied for cosmetics ingredients, especially when the product has microbiological parameters or specifications.

Additional certifications covering quality management, and which are internationally recognized, such as ISO 9001, also contribute to the reputation of a natural ingredient supplier and can represent a competitive advantage especially among larger (multinational) buyers.

The implementation of Good Manufacturing Practices (GMP) for natural ingredients for cosmetics, based on the guidelines of the European Federation for Cosmetic Ingredients (EFfCI) could also be an additional competitive advantage. However, there are costs involved, and European buyers will not always require it. Before engaging in such initiatives, consult the relevance with your potential European buyer.

7.2 Documentation requirements

The documentation requirements for different natural ingredients for cosmetics like essential oils and resinoids varies widely according to the level of knowledge / familiarity of a specific ingredient to the European market and to a specific European buyer. If an ingredient is well-established on the European market, the efficacy and safety data are most probably well studied and understood, and a supplier will not have to conduct further tests.

However, if a supplier is introducing new ingredients to the market, they will have to compile a **ingredient dossier** which contains and evidences all its safety and efficacy data prior to its introduction to the market. The data used in the compilation of a dossier

100. https://apps.who.int/iris/handle/10665/42783

are derived from a supplier's own research and/or from secondary sources of public domain; example: the safety and efficacy of your ingredient, history of use, production methods and any other relevant information[101].

A useful guide for the preparation of a dossier for natural ingredients for cosmetics is the **Workbook for preparing a technical dossier for cosmetic ingredients: vegetable oils, essential oils and botanical extracts[102]**, compiled by Andrew Jones (Fair Venture Consulting)[103] and ProFound – Advisers In Development[104] for the Dutch Center for the Promotion of Imports from Developing Countries (CBI)[105].

This guide explains the different elements which a dossier should contain.

The 3 essential documents required by buyers of essential oils and resinoids in the European Union are[106]:

- *Technical Data Sheet (TDS)*
- *Certificate of Analysis (CoA)*
- *Safety Data Sheet (SDS)*

The information that must be included, as well as the instructions on how to prepare these documents, can be found on the **Workbook for preparing a technical dossier for cosmetic ingredients: vegetable oils, essential oils and botanical extracts[107]**. In general, the content of these 3 documents for essential oils and resinoids consist of the following elements:

Technical Data Sheets (TDS)	Certificate of Analysis (CoA)	Safety Data Sheets (SDS)
• Product name, Description and aroma • INCI name • CAS number • EINECS number • Simplified description of manufacturing process • Organoleptic aspects • GCMS composition (using gas chromatography-mass spectrometry) • % Impurities • Moisture	• Product name • Description and aroma • INCI name • CAS number • EINECS number • Organoleptic aspects • GCMS composition (using gas chromatography-mass spectrometry) • % Impurities • Moisture • Specific gravity • Flash point	• Product name • Description and aroma • INCI name • CAS number • EINECS number • Concentration levels of the 26 allergens (usually a separate declaration) • Flash point • Published studies, reports, references on safety and efficacy • Toxicological tests

101. https://www.cbi.eu/market-information/natural-ingredients-cosmetics/how-prepare-technical-dossier-cosmetic-ingredient
102. https://www.cbi.eu/market-information/natural-ingredients-cosmetics/how-prepare-technical-dossier-cosmetic-ingredient
103. https://www.fairventure.com
104. https://thisisprofound.com
105. https://www.cbi.eu
106. https://www.cbi.eu/market-information/natural-ingredients-cosmetics/how-prepare-technical-dossier-cosmetic-ingredient#setting-up-your-dossier
107. https://www.cbi.eu/market-information/natural-ingredients-cosmetics/how-prepare-technical-dossier-cosmetic-ingredient

Technical Data Sheets (TDS)	Certificate of Analysis (CoA)	Safety Data Sheets (SDS)
• Concentration levels of the 26 allergens (usually a separate declaration) • Specific gravity • Flash point • Optical rotation • Miscibility in ethanol • Toxic components (names, concentration) when applicable • Pesticide residues • References to ISO standards – if applicable • Shelf life under stated conditions • Type of packaging • Recommended storage • Access permits (ABS) and other certifications	• Toxic components (names, concentration) when applicable • Pesticide residues (periodic, not for each batch) • References to ISO standards – if applicable	• Local toxicity • Primary skin irritation • Ocular irritation • Allergenicity • Sensitisation • Systemic toxicity • Mutagenesis: Ames test • Acute toxicity • Efficacy studies (own, published) • Efficacy data summary • Summary of safety data • Recommended conditions of use: product type, part of body, frequency of use, method of application, concentration in cosmetic products • Environmental data **This information must be compiled and presented according to the 16 sections of the Globally Harmonized System (GHS)[108].**

Other documentation which may be required by EU buyers of essential oils and resinoids include:

- *Animal Non-Testing Declaration* Note that the article 4a (2.3) EU cosmetics directive provides the regulatory framework for the phasing out of animal testing for cosmetics purposes, applicable both to ingredients and finished products[109].
- *Allergen declaration*
- *CMR declaration* (non-mutagenic, carcinogenic, toxic)
- *BSE/TSE declaration*
- *Heavy metals declaration*
- *Non-Nanoparticles declaration*
- *IFRA Certificate of Conformity*

7.3 Packaging and Transport

For the packaging of essential oils and resinoids, particularly those classified as hazardous substances and that contain a UN number, the use of packaging approved by the United Nations (UN-approved) is a basic requirement of buyers in the European Union. To obtain specific information on UN-approved packaging and transport of these substances refer to the UN Recommendations on the Transport of Dangerous Goods[110].

Some essential oils and resinoids are classified under Class 3 (flammable liquids, UN number: 1169 extracts, aromatic, liquid; UN number: 1993,

108. https://echa.europa.eu/documents/10162/23047722/guidance_sds_v40_peg_en.pdf/42dc8be5-b033-3062-8ee8-6d3a1b8dcb99
109. https://ec.europa.eu/growth/sectors/cosmetics/animal-testing_en
110. https://unece.org/rev-21-2019

flammable liquid) and Class 9 (miscellaneous dangerous substances and articles, including environmentally-hazardous substances; UN number: 3082: environmentally hazardous substance, liquid, n.o.s.)[111]. The specific hazards association to specific essential oils and resinoids should be verified on the inventory of the European Chemicals Agency (ECHA)[112]. For each class and category, there are specific recommendations in terms of packaging, packaging materials, instructions and restrictions to be applied in the storage and transportation of substances; example:

UN number	Name and description	Class or division	Subsidiary hazard	UN packing group	Special provisions	Limited and excepted quantities		Packagings and IBCs		Portable tanks and bulk containers	
								Packing instruction[113]	Special packing provisions	Instructions [114]	Special provisions[115]
1169	Extracts, aromatic, liquid	3	-	II	-	5 L	E2	P001 IBC02	-	T4	TP1 TP8
1169	Extracts, aromatic, liquid	3	-	III	223	5 L	E1	P001 IBC03 LP01	-	T2	TP1
1993	Flammable liquid, n.o.s.	3	-	I	274	0	E3	P001	-	T11	TP1 TP27
1993	Flammable liquid, n.o.s.	3	-	II	274	1 L	E2	P001 IBC02	-	T7	TP1 TP8 TP28
1993	Flammable liquid, n.o.s	3	-	III	223 274	5 L	E1	P001 IBC03 LP01	-	T4	TP1 TP29
3082	Environmentally hazardous substance	9	-	III	274 331 335 375	5 L	E1	P001 IBC03 LP01	PP1	T4	TP1 TP29

As several essential oils and resinoids are classified as hazardous substances, and their packaging and transport are highly regulated, there are practical consequences to suppliers of these ingredients. European buyers expect their suppliers to understand the Globally Harmonized System (GHS) well, and to apply these concepts in the packaging and transportation of their ingredients.

It is important that the packaging used for essential oils and resinoids does not interact with its contents, and that it is chemical-resistant. As such, the use of plastifiers is not allowed. The industry standard for the packaging and transport of essential oils and resinoids is stainless steel drums with an internal epoxy lacquer coating, or aluminum drums with an internal coating that prevents oxidation of the ingredient.

8. Final recommendations

- Read more about the regulatory framework, buyer requirements and market developments for essential

111. https://unece.org/fileadmin/DAM/trans/danger/publi/unrec/rev21/ST-SG-AC10-1r21e_Vol1_WEB.pdf
112. https://echa.europa.eu/information-on-chemicals/cl-inventory-database/
113. https://unece.org/DAM/trans/danger/publi/unrec/rev18/English/Rev18_Volume2.pdf
114. https://unece.org/DAM/trans/danger/publi/unrec/rev18/English/Rev18_Volume2.pdf
115. https://unece.org/DAM/trans/danger/publi/unrec/rev18/English/Rev18_Volume2.pdf

oils in the European Union:

- Council of Europe: *Guidance on Essential Oils in Cosmetic Products*[116]
- Centre for the Promotion of Imports from Developing Countries (CBI): Market Information on Natural Ingredients for Cosmetics[117]
- Import Promotion Desk (IPD): Market Information on Essential Oils and Vegetable Oils[118]

- Consult official data sources in the European Union to learn more about the regulatory requirements:
  - European Commission[119]
  - EUR-LEX[120]
  - Access2Markets[121]
  - The European Chemicals Agency (ECHA)[122]
- Follow industry-wide discussions and regulatory updates by checking the website of industry associations:
  - European Federation of Essential Oils (EFEO)[123]
  - European Flavour Association (EFFA)[124]
  - International Organization of the Flavour Industry[125]
  - International Fragrance Association[126]
- Comply with the minimum legislative requirements for essential oils and resinoids in the European Union:
  - Do not export threatened species, and their derivatives, which are listed in CITES or in the Annexes of the European Union's Wildlife Trade Regulations, or comply with the necessary export permits. Find out whether a species is listed in these Annexes by directly accessing Regulation (EU) No. 1320 / 2014[127] and the Species+ website of the United Nations Environment Programme - World Conservation Monitoring Centre (UNEP-WCMC)[128].
  - Comply with the Nagoya Protocol in Colombia and in the European Union by understanding its implementation mechanisms and by monitoring your value chain from source to market. Facilitate information to your potential

116. https://www.edqm.eu/en/guidance-essential-oils-cosmetic-products
117. https://www.cbi.eu/market-information/natural-ingredients-cosmetics
118. https://www.importpromotiondesk.com/en/media-center/market-information
119. https://ec.europa.eu/growth/sectors/cosmetics/legislation_en
120. https://eur-lex.europa.eu/homepage.html
121. https://trade.ec.europa.eu/access-to-markets/en/home
122. https://echa.europa.eu
123. https://www.efeo.eu
124. https://effa.eu
125. https://iofi.org
126. https://ifrafragrance.org
127. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014R1320
128. https://www.speciesplus.net

(European) buyer.

- Do not export prohibited substances, and respect the specific limits of constituents where applicable.
- Make sure to provide the necessary technical information to your potential European buyer, and to facilitate any other documentation which will allow the importer and final buyer to comply with their legal obligations in the European Union. Provide a Technical Data Sheet (TDS), Certificate of Analysis (CoA) and a Safety Data Sheet (SDS), as well as other documentation required, complying with the necessary parameters.
- Comply with the requirements of the Classification, Labelling and Packaging (CLP) regulation by classifying, packaging, labelling and transporting your products according to the Global Harmonized System (GHS).
- Carry out the necessary analysis (gas chromatography) of your essential oils and resinoids by an accredited laboratory, and provide your potential European buyers with an IFRA Certificate of Conformity, if applicable.
- Collaborate with universities and other technical and research institutions for the elaboration of studies and documents that can evidence the efficacy, safety and performance of your ingredient(s), and organize this information into a dossier.

- For exporters of essential oils and/or resinoids that fall under REACH regulation: competitive advantage especially among larger (multinational) buyers.

  - Prior to engaging in the registration process, verify whether your potential European buyer demands more than one tonne of your product per year. Ingredients traded in less than one tonne per product, per company, are exempted from the REACH regulation.
  - If your potential European buyer requires you to present a REACH Certificate of Compliance, search for an authorized and qualified EU-based "only representative"[129] to fulfill these duties.
  - Seek collaboration with other Colombian companies handling the same ingredient and engage in a collective process for its registration and authorization required by the REACH regulation. Not only can this lower the actual costs, but also facilitate processes such as the compilation of the necessary information for technical and scientific dossiers.

129. https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/reach/Only+Representative+of+non-EU+manufacturer

- Comply with requirements related to quality management and Environment, Safety and Health (EHS): (European) buyer.

  - Implement processes of Hazard analysis and critical control points (HACCP) in the manufacturing plant, based on the *Codex Alimentarius*; the implementation of HACCP should be evidenced by a flow chart and possibly through a certificate. This is a minimum requirement for food ingredients (example: flavourings), but it is also commonly applied for cosmetics ingredients, especially when the product has microbiological parameters or specifications.
  - Consider the implementation of quality and safety management systems. For example, ISO 9001 can represent a competitive advantage for specific European buyers, particularly larger companies. The Guide on Good Manufacturing Practices (GMP), of the *European Federation for Cosmetic Ingredients* (*EFfCI*), according to ISO 221716 (Good Manufacturing Practices for Cosmetics) could also represent a competitive advantage for some buyers. It is recommended, however, that you first study your target market and buyer before engaging in auditing and de facto certification processes, which can be very costly.
  - Consider alliances with producers of organic raw material whose organic certification complies with the European Union's legislation, and who comply with Good Agricultural Practices. This will help you mitigate the risks associated with cross-contamination from synthetic inputs and to enable you to target specific markets in Europe (i.e. the growing market for organic essential oils).

- Explore other buyer requirements:

  - Identify other voluntary requirements according to your target market and buyer. Pay specific attention to sustainability requirements which may serve as a competitive advantage as a supplier. This can include certifications such as COSMOS[130] and NaTrue[131] or membership in sustainability platforms such as SEDEX[132].

130. https://www.cosmos-standard.org
131. https://www.natrue.org
132. https://www.sedex.com

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