Guidance on

ESSENTIAL OILS IN COSMETIC PRODUCTS

European Committee for Cosmetics and Consumer Health (CD-P-COS)

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Guidance on

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2nd Edition

European Directorate for the Quality of Medicines & HealthCare (EDQM)

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1. Introduction

Essential oils have become an integral part of everyday life. They are used in a variety of ways, as flavouring agents in foods, for example, or as fragrances or for their many other properties in cosmetic products. Some might believe that all natural essential oils are completely safe, possibly based on the misconception that all plants are safe because they are 'natural'. However, the toxicity of an essential oil may be entirely different to that of the plant from which it is extracted, due to its specific physico-chemical profile and its high concentration in certain compounds. For example, essential oils produced by distillation, are mixtures of mainly low molecular-weight chemical substances. As they are also lipophilic, they are able to pass across membranes very efficiently.

Many essential oils that are considered to be nontoxic can have harmful effects in certain cohorts of people. These effects can be influenced by prior sensitisation to a given essential oil, or to a group of essential oils containing similar components, or to some adulterant within the essential oil. Owing to the influence of age on skin structure and metabolism, the very young and those of the older population may be particularly vulnerable to the harmful effects of topical products. With this in mind, caution is recommended when using essential oils in cosmetic products.

1.1. Aim and target audience

The purpose of this guide is to address the quality factors and risks associated with the use of essential oils in cosmetic products. For instance, section 3 highlights the importance of the quality of essential oils and of the plant raw materials from which they are obtained, and section 4

provides recommendations for the risk assessment of essential oils and how this should be addressed when including them in cosmetic products.

This document is intended for economic operators and, in particular, Responsible Persons (RP) in the cosmetics industry whose obligations are to ensure the safety of cosmetic products in accordance with European and national cosmetic legislative frameworks. This includes, but is not limited to, operators who manufacture, contract the manufacture of, or import cosmetic products containing essential oils. It is also designed to support safety assessors carrying out the safety assessment of cosmetic products containing essential oils, as well as competent authorities reviewing these assessments.

Pure essential oils sold directly to consumers are not addressed in this guide.

1.2. Scope

From the outset, it should be noted that this guide specifically relates to the use of essential oils in cosmetic products that meet the definition of a cosmetic product laid down in Article 2 of Regulation (EC) No 1223/2009, as amended (the 'EU Cosmetics Regulation') [1]. If there is uncertainty as to whether a product meets the aforementioned definition, it may be appropriate to contact the relevant National Competent Authority. This may be important as specific national legislation may apply in certain member states.

It should also be borne in mind that where an ingredient's concentration, function or claim comes under the scope of Directive 2001/83/EC, as amended, relating to medicinal products, it is therefore not a cosmetic product. This is particularly relevant where there is a borderline uncertainty regarding classification of a product or between essential oil ingredients used in cosmetic products and those used in herbal medicinal products.

The Manual of the Working Group on Cosmetic Products, (Sub-Group on Borderline Products) on the Scope of Application of the Cosmetics Regulation (EC) No 1223/2009 (Art. 2(1)(A)) [2], includes entries with relevance to the use of essential oils regarding potential 'borderline products',

for example in relation to aromatherapy products and products containing pure essential oils.

The European Union (EU) herbal monographs available on the European Medicines Agency (EMA) [3] website may also be a useful resource.

1.3. Definition of essential oils

Whilst essential oils are not defined in the EU Cosmetics Regulation, there are a number of definitions of essential oils within other product categories. Essential oils may be composed of various substances, typically mixtures of liquid, volatile and fat-soluble plant ingredients or of synthetic aromatic substances with a characteristic fragrance. In contrast to fatty oils, essential oils evaporate. The mixtures consist of several chemical compounds most of which, chemically, are terpenes and their derivatives [4].

The European Chemicals Agency (ECHA) defines an essential oil as 'a *volatile part of a natural product, which can be obtained by distillation, steam distillation or expression in the case of citrus fruits. It contains mostly volatile hydrocarbons. Essential oils are derived from various sections of plants. The oil is "essential" in the sense that it carries a distinctive scent, or essence of the plant*' [5].

The International Organization for Standardisation ISO 9235: 2021(E) standard *Aromatic natural raw ingredients – Vocabulary* includes a generic definition of 'essential oil' together with other definitions for essential oils that have been obtained by specific extraction processes or treatments, for example [6].

Perhaps the most complete definition in terms of application to public health is that adopted by the European Pharmacopoeia Commission and published in the European Pharmacopoeia (Ph. Eur.), in relation to the use of essential oils in medicinal products [7]:

> *'Odorous product, usually of complex composition, obtained from a botanically defined herbal drug by steam distillation, dry distillation, or a suitable mechanical process without heating. If an aqueous phase is present, the essential oils are separated from it by a physical process that does not significantly affect their composition.*

Essential oils obtained from the primary production steps may be subjected to a suitable subsequent treatment in order to remove unwanted matter (e.g. insoluble matter) or remaining water, without significantly affecting their composition.'

The Ph. Eur. goes on to describe how an essential oil may be subjected to further processing steps (combining, rectification, etc.) that may or may not significantly affect its composition.

'An essential oil whose composition has been significantly modified may be known as:

- *Rectified essential oil: an essential oil from which part of the constituents has been partially or totally removed by rectification;*
- *Deterpenated essential oil: an essential oil from which monoterpene hydrocarbons have been partially or totally removed by rectification or any other suitable process;*
- *Deterpenated and desesquiterpenated essential oil: an essential oil from which monoterpene and sesquiterpene hydrocarbons have been partially or totally removed by rectification or any other suitable process;*
- *'X'-free or partially 'x'-free essential oil: an essential oil from which one or more particular constituents have been totally or partially removed by rectification or any other suitable process.'*

Where a relevant monograph of the Ph. Eur. refers to obtaining an essential oil from a *'defined herbal drug'*, in terms of cosmetic products, this reference to a herbal drug could be considered as a *defined plant raw material*.

It should be noted that the above definition should be considered in conjunction with Ph. Eur. general chapter *5.30. Monographs on essential oils (information chapter)* [8] which, amongst other details, provides further information on the use and impact of distillation and rectification processes.

Furthermore, the European Directorate for the Quality of Medicines & HealthCare (EDQM, Council of Europe) has published guidance on the elaboration of monographs on herbal drugs and herbal drug preparations [9], which includes a section (III.B) devoted to essential oils.

Only essential oils that satisfy the Ph. Eur. definition are considered in this document, as synthetic substances are not included. From a toxicological point of view, however, there may be no difference between a natural and a synthetic molecule.

2. Regulatory context and relevant guidance

2.1. EU Cosmetics Regulation (EC) No 1223/2009, as amended

As previously stated, in the EU, cosmetic products are regulated by the EU Cosmetics Regulation. This regulation includes certain provisions that specifically address the use of essential oils in cosmetic products, most notably in its Annexes II and III. The onus is on RPs to ensure that the products they place on the EU market meet these regulatory requirements, as stated in Article 5 of the Regulation. It is important to note that the Annexes to the EU Cosmetics Regulation are regularly updated.

The EU Cosmetics Regulation also requires the RP to ensure that a cosmetic product has undergone a safety assessment, by an appropriately qualified safety assessor and on the basis of the relevant information, prior to placing the cosmetic product on the market. A safety report must be drafted in accordance with Annex I. Guidelines for Annex I are laid down in the Commission Implementing Decision 2013/674/EU [10]. Additional information relevant to cosmetic product ingredients is also available in the Council of Europe publication relating to ingredients used in cosmetics [11].

Annex II to the EU Cosmetics Regulation lists substances that are prohibited for use in cosmetic products. These include:

- certain plant ingredients that are prohibited in cosmetic products, regardless of their function;
- plants and their compounds that are prohibited in cosmetic products for a given function (fragrance ingredients);
- substances that are prohibited in cosmetic products unless they are naturally present in extracts;
- and essential oils that are subject to concentration limits.

In general, the unintentional presence of a small quantity of prohibited substance, stemming from natural ingredients, for example, is permitted when it is technically unavoidable in good manufacturing practice, provided that such presence is safe for human health (Article 17 of the EU Cosmetics Regulation).

Annex III to the EU Cosmetics Regulation lists substances that cosmetic products must not contain except subject to the restrictions laid down. This includes restrictions in relation to the use of a number of oils and extracts. Furthermore, Annex III lists substances, known as fragrance allergens, subject to mandatory labelling conditions due to their allergenic potential. Their presence in cosmetic products must be mentioned in the list of ingredients 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.

It should be noted that according to Article 15 of the EU Cosmetics Regulation, the use of substances classified as category 1A, category 1B or category 2 carcinogenic, mutagenic or toxic for reproduction, under Part 3 of Annex VI to Regulation (EC) No 1272/2008 ('CMR substances'), is prohibited in cosmetic products. However, such CMR substances may be used in cosmetic products where the specific conditions laid down in Article 15(1) and Article 15(2) of the EU Cosmetics Regulation are fulfilled. The CMR substances web page of the European Commission (EC) website has information in relation to this topic [12].

The Scientific Committee on Consumer Safety (SCCS) published an opinion on fragrance allergens in cosmetic products in June 2012 [13], evaluating essential oils and their effects as contact allergens in humans. Related to this SCCS opinion, an impact assessment study on fragrance labelling on cosmetic products was also carried out in 2020 [14].

2.2. Recommendations of the Council of Europe

The Council of Europe has published three volumes of recommendations concerning the use of plants and plant-based preparations as ingredients in cosmetic products, as an increasing number of plant-based cosmetic products have been placed on the market [15-17]. These are in addition to the publication relating to a safety survey of ingredients used in cosmetic

products [11] and the recommendations concerning the use of camphor, eucalyptol and menthol, i.e. that their use should be avoided in infants [18].

The three volumes contain a number of datasheets on plants and plant preparations that have been evaluated by the Council of Europe's Committee of Experts on Cosmetic Products. The entries are classified into three categories: plants that do not present a health hazard; those for which further information is needed; and those that may pose a health risk and are not recommended for use in cosmetic products.

Despite the long history of use of natural raw materials such as plants and plant preparations in cosmetic products, the Council of Europe's Committee of Experts on Cosmetic Products highlighted the fact that some of these raw materials contain substances with significant activity, that could be potentially harmful for consumers. This risk must be taken into consideration when evaluating the overall safety of a cosmetic product.

2.3. Recommendations of the European Chemicals Agency

Suppliers of essential oils to cosmetic product manufacturers should note that there may be relevant regulatory requirements in relation to the REACH Regulation (EC) No 1907/2006 [19] and CLP Regulation (EC) No 1272/2008 [20]. The appropriate classification and identification of such essential oils as chemical substances should be considered. For example, the ECHA published guidance regarding the identification and naming of substances under REACH and CLP [21]. Appropriate due diligence should be carried out with the relevant National Competent Authorities and with the ECHA to ensure regulatory compliance of any such essential oils.

2.4. Examples of specific national legislation and recommendations

France

- Recommendations regarding essential oils quality criteria (May 2008) [22].

- Recommendations to manufacturers and responsible persons for the placing on the market of cosmetic products containing terpenoids: camphor, eucalyptol, menthol (August 2008) [23].
- Recommendations for the risk assessment associated with the use of essential oils in cosmetic products (October 2010) [24].

Germany

- The Federal Institute for Risk Assessment (BfR) recommended [4] maximum concentrations of camphor, eucalyptus oil, menthol and methyl salicylate in leave-on products and maximum concentrations of camphor, menthol and methyl salicylate in rinse-off products.
- The BfR has published an opinion [25] recommending a concentration limit for tea tree oil in cosmetic products.

2.5. Recommendations of the International Fragrance Association (IFRA) and European Federation of Essential Oils (EFEO)

The IFRA represents the collective interests of its members and supports those of the finished fragrance products community. The IFRA Code of Practice [26] obliges the members to adhere to good operating practices, apply IFRA Standards [27] that limit or ban the usage of certain fragrance materials and ensure safe use and regulatory compliance.

IFRA, in conjunction with the Research Institute for Fragrance Materials, collects data and makes it available for the safety evaluation of fragrance ingredients. As many fragrances contain essential oils and their components, this information should be considered by operators incorporating essential oils into cosmetic products. However, it is to be noted that reliance on the proposed IFRA concentrations alone may not be sufficiently rigorous to ensure the safety of a compound in a cosmetic product, and that a Certificate of Conformity to IFRA Standards does not replace the cosmetic product safety assessment.

The EFEO aims to represent producers and traders of essential oils and related products within Europe. IFRA and EFEO have published joint guidance, the EFEO/IFRA Guidelines on substance identification and sameness

of natural complex substances (NCS) under REACH and CLP, on the determination of the chemical identity of natural complex substances, including essential oils [28].

3. Quality of essential oils

The safe use of essential oils in cosmetic products depends on both the quality of the raw materials used and the extraction method by which the pure essential oil is produced. The specific physical and chemical characteristics of essential oils should be identified and the oils should be stored in well-filled, airtight containers, protected from light and heat.

The physical, organoleptic, chemical and chromatographic characteristics of essential oils are set globally through various ISO standards. There are also ISO standards relating to the nomenclature and the general rules for packaging, conditioning and storing essential oils [28-31] and labelling and marking of their containers [32].

It is important to remember that the safety assessment, as discussed in section 4, relies heavily on the consideration of the constituents of essential oils, and their concentrations. Setting quality specifications of the oils and the original plant raw materials is an important part of this process. The safety assessor must have accurate information concerning those quality specifications and the information must reflect the substances or mixture that will be used in the manufacture of marketed product. Setting quality specifications is also relevant for the product's batch-to-batch consistency to help ensure that the information reviewed by the safety assessor remains valid. Any changes to the quality of the raw materials or essential oils used may result in the need for reassessment by the safety assessor.

3.1. Plant raw materials

According to Ph. Eur. general monograph *2098* [7], the plant raw material may be fresh, lightly wilted, wilted, partially dried, dried, whole, fragmented, broken or cut. Individual monographs of the Ph. Eur. for specific essential oils may describe quality requirements for the plant raw material.

General monograph *2098* [7] also states that different batches of the plant raw material (herbal drug) may be combined prior to processing, for example to achieve the quantity required for the production process.

The EMA's Committee on Herbal Medicinal Products has published a guideline on good agricultural and collection practice for starting materials of herbal origin [33]. Although this document applies to the agricultural production, collection and primary processing of medicinal plants/herbal substances that are used for medicinal purposes, the recommendations may be useful to those preparing herbal substances for cosmetic purposes.

3.1.1. Botanical name

The identity of the plant must be precisely defined by its scientific botanical name according to the International Code of Nomenclature for Cultivated Plants rules. The international name of a plant, expressed in Latin, includes the genus name followed by the species name, and the initial or abbreviation of the botanist who first described the plant in question. Where appropriate, it is completed by the subspecies or variety name. The botanical family is usually specified. The accuracy of the name is significant. Differences in chemical composition can occur depending on the botanical origin [34].

An example of a scientific botanical name from the Lamiaceae family would be *Lavandula angustifolia* Mill., in which *Lavandula* refers to the genus, *angustifolia* refers to the species and Mill. refers to the botanist's name (Miller). Further examples can be found below.

Genus

E.g.: *Lavandula* and *Mentha*.

Species

Two very similar species, from the same genus, may give essential oils with different chemical compositions.

E.g.: True lavender (*Lavandula angustifolia* Mill.); Spike lavender (*Lavandula latifolia* Medik.).

In most cases, each species has a unique chemical profile but it is possible for two species to be sources of essential oils with very similar compositions.

E.g.: Anise (*Pimpinella anisum* L.); Chinese star anise (*Illicium verum* L.).

Subspecies

Some species have a number of subspecies.

E.g.: Bergamot (*Citrus aurantium* L. ssp *bergamia* (Wight & Arnott) Engler); Bitter orange (*Citrus aurantium* ssp *aurantium* L.).

Variety

Within a species, there may be varieties with different essential oil compositions.

E.g.: the species basil (*Ocimum basilicum*) is morphologically and chemically very heterogeneous and is divided into many varieties that are difficult to differentiate (*O. basilicum* var. *basilicum*, *O. basilicum* var. *misshapen* Benth., *O. basilicum* var. *glabratum* Benth.)

Because of possible confusion due to the existence and/or current use of many synonyms, it is necessary to refer to ISO standard 4720: 2018 [30], which gives a list of the botanical nomenclature of plants used for the production of essential oils with the common names of essential oils in English and French. This standard also includes an alphabetical index of common names of essential oils.

3.1.2. Conditions for the production of the plant raw material

As growing conditions, harvesting, drying, milling and storage have an impact on the quality of the plant, which in turn may affect the quality of the essential oil, these factors need to be considered.

Plant raw materials are obtained from either gathering or harvesting plants; the latter can be grown from seedlings or cuttings. Plant raw materials should be, as far as possible, free from impurities such as dirt, dust, and fungal infections or animal contamination. They should show no sign of rot or damage.

The wild state or culture conditions and environmental factors play a significant role, not only on the quantitative but also on qualitative aspects of the constituents produced by the plant. Therefore, the availability of information on the geographical and environmental conditions under which the plant grows (e. g. use of pesticides) and how the oil is produced is essential. Other parameters such as the exact location of culture, altitude, nature and degree of fertilisation and its stage of vegetation should also be considered. Over time (seasons, months or days), biosynthesis may cause a plant raw material to contain significantly more or less of some metabolites.

In order to inhibit enzyme activity, which can cause the degradation of some constituents, after harvest and to prevent microbial growth, the plant raw material must undergo either immediate distillation or careful drying. It must be demonstrated that none of the treatment steps to which a plant raw material is subjected alters the plant constituents or leaves harmful residues.

3.1.3. Part of plant used

Essential oils are found almost exclusively in higher plants. The genera capable of developing the constituents present in an essential oil are distributed amongst a limited number of families (e.g., *Apiaceae*, *Asteraceae*, *Cupressaceae*, *Lamiaceae*, *Lauraceae*, *Myrtaceae*, *Poaceae*, *Rutaceae*, etc.).

The essential oils can accumulate in all types of plant organs but mainly come from the flower and leaf components. Some examples are outlined below:

- flowers (orange, rose, lavender)
- leaves (citronella, eucalyptus, bay laurel)
- bark (cinnamon)
- woods (rosewood, camphor, sandalwood)
- roots (vetiver)
- rhizomes (curcuma, ginger)
- dried fruits (anise, star anise, parsley)

- seeds (nutmeg).

In some cases, all the plant organs of the same species may contain essential oils; however, the qualitative and quantitative composition may vary depending on the location of these organs in the plant.

Biosynthesis and accumulation of aromatic molecules are usually associated with the presence of specialised histological structures such as glandular trichomes, secretory cells, secretory cavities, resin ducts, etc. that are often located on or near the surface of the plant [33].

3.1.4. Accuracy of chemotype

A given botanical species may have several chemotypes that have slight differences in biosynthetic pathways. This phenomenon has been well studied for thyme (*Thymus vulgaris* L.) for which there are at least seven different chemotypes (such as alpha-terpineol, carvacrol, cineole, geraniol, sabinene hydrate, linalool, thymol) [35].

For some species, it is therefore essential to have information relating to the specific chemotype as it can determine the activity and/or toxicity of the essential oils present.

The information chapter published in the Ph. Eur. [8] gives examples of potential reasons for the existence of different chemotypes, such as the origin of the plant material, the chemical composition, or the primary processing.

3.1.5. Identification

The identity of the initial plant raw material is required to ensure traceability through to the use in cosmetic products. This identity can be established through the provision of licences (if applicable) or documented commitments from the supplier or through one or more of the techniques described below:

- macroscopic botanical characteristics: comparison of the plant raw material with a reference description to allow for rapid identification of the substances;

- microscopic botanical characteristics: microscopic examination of the plant, to search for and identify specific or dominant characters. This examination enables operators to identify the presence of foreign elements;
- thin-layer chromatography or gas chromatography: the chromatogram of the test solution obtained by extraction is compared to a control solution comprising preferably two reference substances (TLC), or to a chromatographic profile (GC);
- chemotype characterisation: this should be done after identification of the major constituents in the essential oil under analysis.

Analysis of the plant raw material may also include the determination of total ash, loss on drying or water content (determined by distillation).

Other quality factors relating to pesticide residues and microbiological quality (number and types of micro-organisms) should be verified.

It may be of interest to note that often the approach in Ph. Eur. monographs is to have two sets of identification tests for essential oils [9].

3.2. Essential oils

3.2.1. Method for extracting essential oils

Essential oils are produced by distillation (steam or dry) or by a mechanical process (cold-pressed oils) [7]. The choice of method for extracting the essential oil depends on the original state and the characteristics of the plant raw material.

The ratio of essential oil to plant raw material can be highly variable depending on the plant and can range from 0.015 % to more than 20 % [35]. To give an example of this variability, 10 kg of fresh lemon balm leaves yields 1.5 g of lemon balm essential oil whereas 10 kg of cloves produces 2.2 kg of clove essential oil.

The extraction method determines the characteristics of the essential oil such as its viscosity, colour, solubility and volatility, and can cause enrichment or depletion of some components. The extraction methods

described below are detailed in general monograph *2098* of the Ph. Eur. [7] and further explained in the related information chapter [8].

Steam distillation

The essential oil is produced using steam and suitable distillation equipment. The steam may be introduced from an external source or generated by boiling water below the plant material or by boiling water in which the plant material is immersed. The steam and oil vapours are condensed. The water and essential oil are then separated by decantation or any other suitable physical process. The filtration or other processes carried out to remove unwanted matter do not significantly affect the composition of the essential oil.

Dry distillation

The essential oil is produced by heating the plant (herbal drug) at high temperature in suitable equipment without adding water or using steam.

Mechanical process

The essential oil, usually known as 'cold-pressed', is produced by a mechanical process without any heating. It is mainly applied to citrus fruits and involves expressing the essential oil from the pericarp, followed by separation using suitable physical means.

Rectification

The essential oil is subjected to distillation, usually under vacuum. This additional processing step can be applied to remove, partially or totally, water or any other unwanted matter (such as insoluble matter or waxes etc.), or to significantly modify the composition. It is therefore described in the Ph. Eur. that:

- rectification can be used without significantly changing the composition of the essential oil; *or*
- rectification can be used to bring about a significant change in the composition of the essential oil. For example, it may enrich an

essential oil of a particular component, or be used to remove, partially or wholly, a given constituent.

Other separation processes, such as crystallisation, can also be used for total or partial removal of a constituent of an essential oil.

3.2.2. Physico-chemical characteristics

Essential oils are typically volatile substances that are liquid at room temperature; this differentiates them from what are referred to as 'fixed oils'. They are somewhat coloured, and their density is generally lower than that of water. They have a high refractive index and most rotate polarised light. They are soluble in lipids and common organic solvents and can be distilled with steam. Essential oils are very sparingly soluble in water.

They are complex mixtures of various constituents in variable concentrations within defined limits. These constituents mainly, but not exclusively, belong to two groups characterised by distinct biogenetic origins: terpenoids, and substances biosynthesised from shikimic acid giving rise to phenylpropane derivatives.

The individual monographs of the Ph. Eur. give specific detail on the physico-chemical characteristics of each essential oil.

3.2.3. Identification and chromatographic analyses

According to Ph. Eur. information chapter *5.30* [8], essential oils are typically identified and characterised by their gas chromatographic profile. However, chapter *5.30* further states that other analytical approaches would no doubt be required for some cases of adulteration, for example detection of different forms of chiral compounds and fatty oils.

The analysis of essential oils to identify each of the constituents and the test for possible falsifications can be performed using techniques such as gas chromatography on polar, apolar or chiral stationary phases, coupled with mass spectrometry or Fourier transform infrared detection. Isotopic analysis, for example the measurement of $^{13}C/^{12}C$ or $^{18}O/^{16}O$ ratios can also contribute to testing for frauds. The bibliography [36-44] illustrates some techniques for testing and assaying molecules suspected of being

allergenic. It should be noted that some of these references may include information for substances that are prohibited from cosmetic products, as they are listed in Annex II to the EU Cosmetics Regulation. However, this information is still considered useful as it could potentially be used to ascertain that a prohibited substance is not present and help to avoid inadvertent non-compliance with the EU legislation.

According to quality standards such as the monographs of the Ph. Eur. and the relevant ISO publication, the quality of essential oils is assessed by measuring a certain number of indices and by simple chromatographic analyses. The risk of contaminants being present in essential oils is closely linked to the type of contaminants, the origin of the plant material used for production and the product processes; this risk is higher for cold-pressed essential oils than for distilled essential oils [8].

Some examples of testing of essential oils described in the general monograph of the Ph. Eur. are outlined below:

- physical indices: relative density, refractive index, optical rotation, freezing point, evaporation residue, solubility in ethanol, water content;
- chemical values: acid value, peroxide value;
- contamination: fatty oils and resinified essential oils, foreign esters, heavy metals, pesticide residues, aflatoxins, microbial quality;
- chromatographic analyses: thin-layer chromatography, high performance thin-layer chromatography, gas chromatography (using a chiral column if necessary).

The chromatographic profile of an essential oil obtained under specific conditions (capillary column, split or splitless injection mode, flame ionisation detector, preliminary qualification of the installation with a mix of nine compounds), allows analysts to obtain a reproducible estimate of the different characteristic constituents in the essential oil using a standardised method.

In the case of a finished product containing an essential oil and other components, the assay of the constituents to be considered is based on a calibration method requiring the injection of a standard solution containing

each of these constituents at known concentrations, with the appropriate validation.

3.2.4. Conservation and storage conditions

Operators should be aware of the relative instability of the constituents in an essential oil and care should be taken to ensure quality during storage.

Signs of degradation can be easily identified by a number of means such as:

- measuring chemical indices;
- determining physical characteristics (refractive index, optical rotation, miscibility with ethanol);
- chromatographic analysis.

The consequences of degradation are numerous, for example, photoisomerisation, photocyclisation, oxidative cleavage, peroxidation and decomposition of alcohols and ketones, thermal isomerisation, hydrolysis and transesterification.

Degradation can change the properties and potentially jeopardise the safety of the essential oil. In order to avoid such degradation, essential oils should be stored in a clean, dry container that is aluminium glazed, stainless steel or anti-actinic tinted glass and that is almost entirely filled and sealed tightly. The air space in the container could be filled with nitrogen or another inert gas. The storage instructions should indicate that the container must be stored away from heat and light. When storing a cosmetic product containing an essential oil, these precautions should be considered. In addition, serious incompatibilities may exist with some types of plastic packaging, and this should also be taken into account.

In some cases, a suitable antioxidant may be added to the essential oil. In this case, the additive is to be mentioned at the time of the sale or use of the essential oil.

Consideration of appropriate labelling is prudent, for example to ensure clarity with regard to the name of the essential oil, the scientific name of the plant raw material used, the storage conditions, and where applicable

the type and/or chemotype of the essential oil, and name and concentration of any added antioxidant.

If a Ph. Eur. monograph exists for a specific essential oil and it describes specific storage conditions for the oil, it is recommended to apply them for the essential oil used in the manufacture of a cosmetic product; appropriate scientific justification should be provided if this is not considered relevant.

ISO/TS standard 210: 2023 [31] outlines general requirements and guidelines for packaging, conditioning and storage of essential oils, and ISO 211:2023 [32] outlines the general requirements for labelling and marking of containers of essential oils.

4. Risk assessment of essential oils in cosmetic products

It is of the utmost importance to remember that the risk assessment of essential oils in cosmetic products must comply with Annex I to the EU Cosmetics Regulation, and the Guidelines on Annex I according to Commission Implementing Decision 2013/674/EU.

Essential oils are natural plant products that possess, among other qualities, various biological properties. Volatile organic substances of known chemical structure in the essential oils react, either singly or in combination, with biomolecules (proteins, etc.) to produce biological responses that may be responsible for the toxicity observed.

It is often assumed that essential oils are not dangerous because they are obtained from plant raw materials. However, certain essential oils may cause dose-dependent skin reactions or irritate the eyes and mucous membranes. These include, but are not limited to, Ceylon cinnamon, exotic basil, peppermint, clove, niaouli, thyme, marjoram, savory and lemon grass. Symptoms may persist for some days after skin contact with the product. A further example is essential oils used in deodorant spray that may trigger asthma attacks. Accidental oral ingestion of essential oils can cause severe poisoning, leading – depending on the dose – to coma

or even death. Some essential oils are phototoxic, for example lemon, bergamot and bitter orange oils.

Due to the complexity of these natural products, the toxicological and biochemical testing of an essential oil should also take into account the sum of its constituents which can act in an additive or synergistic manner or in an antagonistic way with one another. Fundamentally, it is the interaction between one or more molecules in the essential oil and macromolecules that yields the biological response, regardless of whether it is a desired functional effect, such as a pleasing smell, or having a potential toxic effect. Attention is drawn to the joint opinion from the Scientific Committee on Health and Environmental Risks (SCHER), the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and the SCCS published in 2011 relating to the toxicity and assessment of chemical mixtures [47].

The chemical constitution of an essential oil is fundamental to understanding the factors affecting its safety in a cosmetic product.

The SCCS has published Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation [48].

Risk assessments related to the use of an essential oil as an ingredient in cosmetic products should comply with the cosmetic product assessment process recommended in the SCCS Notes of Guidance. The safety assessment of a cosmetic product (the Cosmetic Product Safety Report) must be reported in its Product Information File and comply with Annex I to the EU Cosmetics Regulation (including relevant national legislation) and the detailed guidance on the cosmetic product safety report that was published in November 2013 [10]. Chapter 3-6.1 of the SCCS Notes of Guidance, Multi-constituent natural ingredients, is of relevance and specifically refers to essential oils.

Due to the complex nature of essential oils, which are generally composed of mixtures of many substances, appropriate supportive or alternative methodologies may be needed. This section presents possible approaches for evaluating the safety of essential oils. However, it must be borne in mind that it is the RPs obligation to implement the necessary means to ensure safety for consumers, and that the safety assessment must be carried out by an appropriately qualified person [1, 10].

In accordance with guidelines for cosmetic products [10, 48], an evaluation of essential oils by a safety assessor could include:

- an analytical phase in which the quantitative composition of the essential oil is determined as exhaustively as possible, by the implementation of appropriately justified analytical methods;
- an extensive literature search concerning the essential oil and its chemical constituents identified during the analytical phase;
- a hazard characterisation of these chemical compounds individually and, when possible, of the mixture comprising the essential oil considered;
- an evaluation of exposure under use conditions (including but not limited to dermal exposure and, owing to the volatile characteristics, inhalation);
- a risk assessment using all the information obtained in the preceding points.

If this data profile is insufficient to perform a risk assessment, it is possible to justify the use by means of an *in silico* structure-activity research approach supplemented by toxicological studies. In all cases, the lack of available safety studies must be justified.

Hazard characterisation may be based on the safety data available for an essential oil and then on the threshold of toxicological concern when there are limited substance-specific toxicity data.

Many essential oils and their constituents have a high sensitising potential. Sensitisation can occur via dermal exposure or by inhalation. The SCCS's opinion on fragrance allergens in cosmetic products systematically and critically reviews the scientific literature to identify fragrance allergens, including natural extracts, relevant to consumers [13].

Risk assessment of a cosmetic product containing essential oils is based not only on the intrinsic hazard data but also on the exposure to the essential oils in question or their constituents. Local tolerance of mucous membranes, if relevant, should be considered, along with the potential for systemic absorption if used in oral cosmetic products. Although such products are not intended for ingestion, local absorption or inadvertent

ingestion may occur. The exposure data will be defined on a case-by-case basis depending on the product's use. The following parameters should be taken into consideration:

- type of cosmetic product;
- concentration of the substance in the finished cosmetic product;
- amount of product used for each application;
- frequency, duration, area and site of application;
- target population;
- normal and reasonably foreseeable conditions of use;
- potential exposure of the area of application to the sun.

The determination of the concentration of the substance in the finished product should take into account all the sources of this substance. The additivity of substances must be taken into consideration, e.g., when more than one essential oil is present in the cosmetic product or when one or more hydrolates are used in the cosmetic product.

It is necessary to refer to the SCCS guidelines which indicate the average area of application per type of cosmetic product as well as the daily exposure to cosmetic products [48].

For the toxicological profile of essential oils, skin sensitisation is a crucial element. Some essential oils have the potential to cause skin sensitisation, which is a growing concern. The SCCS reported the clinical evidence regarding sensitisation to essential oils in its opinion of 2011 [pages 53-57] [13].

The dose-response relationship between exposure to contact allergens and induction of allergy (i.e., sensitisation) is well established in animal models and by tests in healthy volunteers. It seems that not only the dose per unit area of allergen, but also the number of exposures, i.e., the accumulated dose, is of importance for the risk of induction of contact allergy. The induction of contact allergy is an immunological process (type IV allergy), that is clinically asymptomatic. In the case of continued exposure or re-exposure to a sufficient dose of allergen, elicitation will occur. Elicitation is an inflammatory response (eczema) with clinical symptoms of erythema, induration and, in some cases, vesicles. It was not possible

to provide a safe threshold for natural extracts of concern, as no specific investigations exist and the model providing the general threshold (0.01 %) is based on individual chemicals only. However, the SCCS considers that the maximum use concentration applies to the identified chemicals both if added as chemicals or as an identified constituent of a natural ingredient [48]. This will also reduce the risk of sensitisation and elicitation from natural extracts.

4.1. Approach based on available safety data

The intrinsic hazard characterisation and risk assessment under conditions of reasonably foreseeable use require a sequential approach based first on literature data for the essential oil in question and its chemical components. In the absence of data, toxicological studies must be used to identify and characterise the hazard of the essential oil. There is extensive discussion of this information in the SCCS guidance note [48]. Assessments must be compliant with the provisions of the EU Cosmetics Regulation.

When compiling available safety data, it should be considered if the SCCS may have published an opinion on a specific essential oil. Such opinions can be consulted on the European Commission website [50].

Potentially relevant data may be available at the ECHA website [12]; however, it must be remembered that the EU Cosmetics Regulation prohibits the testing of finished cosmetic products and cosmetic ingredients on animals and prohibits the marketing of finished cosmetic products and ingredients in the EU that were tested on animals (Article 18).

4.2. Approach based on the threshold of toxicological concern

The concept of the threshold of toxicological concern (TTC) may be used for chemically defined substances present at low concentrations for which toxicological data is insufficient, but for which reliable exposure data is available. The TTC was developed to assess substances of unknown toxicity that are present as contaminants in food [51]. It is a probability-based screening tool and TTC values are derived from a database of No Observed Adverse Effect Levels after systemic exposure [51]. The TTC relates to

systemic effects only, not local. Thus, allergy, hypersensitivity, and intolerance – toxicological endpoints of concern for essential oils – are not taken into account.

Additionally, if this concept is used in the field of cosmetic products, appropriate methodologies need to be developed to allow for route-to-route extrapolation from oral to dermal exposure. It should be noted that the TTC approach differs from other alternative approaches because it focuses more on risk assessment (i.e., the establishment of a permissible exposure limit) rather than just on the hazard characterisation.

In the case of essential oils, the TTC approach could be applied to chemically identified constituents present in small amounts, for which the toxicological data is insufficient. However, each constituent within the oil or mixture would need to be taken into consideration for a potential cumulative effect. Furthermore, the safety assessor would need to confirm that the mixture does not contain substances from the exclusion categories for which the TTC approach should not be used, as described in Chapter 3-5.2 of the SCCS Notes of Guidance [48]. Attention is also drawn to the SCCS, SCHER and SCENIHR joint opinion on Use of the Threshold of Toxicological Concern Approach for Human Safety Assessment of Chemical Substances with focus on Cosmetics and Consumer Products [49].

4.3. Finalisation of risk assessment

Based on the data (hazard and exposure) examined by a safety assessor, the conclusion of the expert report must answer the following questions:

- Can the essential oil used in the cosmetic product be considered safe for the consumer?
- Is the essential oil subject to restrictive conditions of use in the cosmetic product?
- Does the essential oil require special conditions of use in the cosmetic product?

It is understood that the assessment of risk for humans of a finished cosmetic product remains the responsibility of an appropriately qualified safety assessor; this includes cosmetic products that contain essential

oils. Elements and procedures used for risk assessment must be explicitly described and the reasoning that led to the conclusion must be clearly justified.

5. Conclusion

This document is intended for economic operators in the cosmetics industry who have a responsibility to ensure the safety of cosmetic products. That includes, but is not limited to, RPs who manufacture, contract the manufacture of or import cosmetic products containing essential oils. It aims to highlight the importance of the quality of essential oils and of the plant raw materials from which they are obtained and to provide recommendations on the risk assessment of essential oils and the potential implications when including them in cosmetic products.

Essential oils have been used for centuries in cosmetic products. This history of use can be a reassuring factor to be taken into account. However, some of these oils may be harmful to consumers when added to cosmetic products due to their potential systemic effects after transdermal absorption or inhalation. The scientific publications available are often limited and may only describe the toxicology of specific pure constituents present in an essential oil, without specifically describing the use of these essential oils in cosmetic products. There is a paucity of reliable clinical toxicological work in this area.

Although essential oils are usually employed in a diluted form in cosmetic products, this is not always the case. Products containing high concentrations of essential oils may be harmful especially in vulnerable populations such as children and sensitised individuals. In addition to this, essential oils can have variable parameters that can significantly alter their chemical profile and therefore increase the risk of toxicity. This in turn could influence the quality and safety of the finished cosmetic product.

It is therefore important to consider the most up-to-date information available and to ensure that defined quality factors exist for essential oils and are considered by all operators when placing such cosmetic products on the market.

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The guidance document aims to address the quality criteria and risks associated with essential oils in cosmetic products and is intended for responsible persons in the cosmetics industry. Revised texts for the second edition were updated and approved by the CD-P-COS (European Committee for Cosmetics and Consumer Health).

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