Expert Panel for Delimitation Questions

Swissmedic, Swiss Agency for Therapeutic Products
Federal Office of Public Health FOPH
Federal Food Safety and Veterinary Office FSVO
Association of Cantonal Pharmacists KAV
Association of Swiss Cantonal Chemists VKCS

Fact sheet: Classification of essential oils – delimitation criteria

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1 Introduction

Essential oils are subject to different laws in Switzerland depending on their intended purpose. Because the classification of such oils and products containing them generates repeated queries to the Swiss Agency for Therapeutic Products (Swissmedic), the Federal Office of Public Health (FOPH) and the Federal Food Safety and Veterinary Office (FSVO), this fact sheet lists the main criteria to be taken into account when classifying these products[1].

The aim is to provide the enforcement authorities with clear guidelines to ensure uniform procedures in Switzerland. For delimitations between these product categories, see the report “Delimitation criteria for medicinal products / foodstuffs regarding products to be taken orally”[2] and guidelines “Delimitation criteria for cosmetic products / therapeutic products and biocidal products”[3].

Products containing essential oils may be sold as medicinal products, medical devices, chemicals or biocides, or in electronic cigarettes, cosmetics and foodstuffs, and be marketed in Switzerland only if they meet the requirements set out below.

2 Essential oils as medicinal products

Medicinal products in accordance with the Swiss Therapeutic Products Act (TPA; SR 812.21) are products of chemical or biological origin that are intended or advertised to have a medicinal effect on

[1] This fact sheet deals with the delimitation criteria for essential oils used in humans. It does not address special requirements such as those regarding the safety of foodstuffs derived from animals.

[2] Link: https://www.blv.admin.ch/dam/blv/de/dokumente/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/hilfsmittel-vollzugsgrundlagen/bericht-abgrenzungskriterien-heilmittel-lebensmittel.pdf.download.pdf/d_Abgrenzungskriterien_Heilmittel_-Lebensmittel_Publikation_def.pdf

[3] Link: https://www.blv.admin.ch/dam/blv/de/dokumente/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/hilfsmittel-vollzugsgrundlagen/leitfaeden-merkblaetter-archiv/lf-abgrenzung-kosmetika-heilmittel-biozide.pdf.download.pdf/2021_final_DE.pdf

the human or animal organism, notably for the detection, prevention or treatment of diseases, injuries and disabilities (see Art. 4 para. 1 let. a TPA).
Therapeutic indications, claims with a medical purpose and designations with a medical meaning, such as “therapy”[4], are reserved for therapeutic products. In principle, medicinal products must be authorised by Swissmedic before being placed on the market (Art. 9 para. 1 TPA).
Accordingly, essential oils as ready-to-use medicinal products must also be authorised by Swissmedic before being placed on the market (Art. 9 para. 1 TPA). The distributor must demonstrate inter alia that the medicinal product is of high quality, safe and effective. Distributors must hold a manufacturing, import or wholesale authorisation from Swissmedic and be domiciled or have a registered office or branch office in Switzerland. Simplified authorisation procedures can be used for certain groups of medicinal products, including essential oils, provided the underlying requirements are met. For further information, visit www.swissmedic.ch.

Essential oils used for the manufacture and supply of medicinal products exempt from authorisation on the basis of Art. 9 para. 2 let. a to c^{bis} TPA (“formula medicinal products”) fall under the supervisory competence of the cantonal authorities.
There is no list of permitted essential oils.

Furthermore, it is the responsibility of the manager of the pharmacy or chemist shop to evaluate the appropriate and safe dosage based on specialist literature (Art. 3 and Art. 26 TPA) and to ensure that the requirements laid down in “Position Paper 0020 – Formula medicinal products: manufacture and placing on the market”[5] are met during manufacture and supply.

3 Essential oils in medical devices

Medical devices are therapeutic products used in or on the human body which achieve their main intended effect via physico-chemical or mechanical means. Medical devices may contain as components supporting substances that have a pharmacological, immunological or metabolic action. These substances include essential oils.

The classification of medical devices containing essential oils as components (and of all other medical devices) is based on Annex VIII to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (“EU-MDR”) in accordance with Art. 15 of the Swiss Medical Devices Ordinance (MedDO; SR 812.213).

If a product is subject to multiple classification rules, the strictest rule applies in each case, resulting in the product being assigned to the highest class.
In the case of medical devices containing essential oils as substances, classification rules 14 and 21 of Annex VIII EU-MDR are of particular relevance.

[4] 2A.693/2005 28.08.2006 - Schweizerisches Bundesgericht (bger.ch)2A.693/2005 28.08.2006 - Schweizerisches Bundesgericht (bger.ch)
[5] Positionspapier 0020 – Formula-Arzneimittel: Herstellung und Inverkehrbringen, current version only in German, link: https://www.kantonsapotheker.ch/de/leitlinien-/-positionspapiere-/-listen/kav-positionspapiere

These two classification rules are not exhaustive[6]. Classification is to be undertaken on a case-by-case basis and depends on the qualitative and quantitative composition of the product, including its component essential oils and their mode of action.
The effects of the product as claimed by the manufacturer must be substantiated by clinical data and references to scientific literature, and detailed in the technical documentation.

4 Essential oils as chemical products

Essential oils that are not used as foodstuffs, for cosmetic purposes, as medicinal products or as medical devices and are not advertised as such are subject to the provisions of chemicals legislation. Typical applications include room fragrances. In the case of chemical products, the responsible distributors must carry out self-regulation[7] prior to marketing. To this end, they must classify and package the chemical product and if necessary, label it with hazard pictograms and hazard and safety information, compile a safety data sheet and register the product in the Chemicals Product Register[8]. Not all essential oils are harmless; they can often contain allergenic or even carcinogenic substances. It is therefore possible for essential oils to fall into Group 1 or 2 with regard to supply provisions[9] under chemicals legislation. This means that suppliers of Group 2 products must have “Specialist knowledge” training and the products may only be supplied under exclusion of self-service. Group 1 products may not be supplied to private individuals or to the general public.

Further information is available at:
www.chemsuisse.ch -> Fact sheet D05
www.cheminfo.ch
https://www.anmeldestelle.admin.ch/chem/en/home/themen/pflicht-hersteller.html
https://www.bag.admin.ch/bag/de/home/gesund-leben/umwelt-und-gesundheit/chemikalien/chemikalien-a-z/aetherische-oele.html

Note: Essential oils are commonly placed on the market improperly under chemicals legislation, despite being openly or covertly advertised by the distributors as medicinal products or foodstuffs (e.g. food supplements). Consumers are emphatically warned against the improper use of essential oils that have been placed on the market under chemicals legislation. In these cases, aspects of purity, efficacy and tolerability do not necessarily meet the requirements and have not been clarified.

5 Essential oils as biocidal products

Essential oils are often claimed to repel insects or to have disinfectant properties. Essential oils used to repel or kill harmful organisms such as mosquitoes, bacteria, etc. must be authorised in accordance with the Swiss Ordinance on Biocidal Products[10]. The authorisation authority is the joint notification authority for chemicals of the Federal Office for the Environment (FOEN), the FOPH and the State Secretariat for Economic Affairs (SECO).

[6] See the 22 classification rules in Annex VIII to Regulation (EU) 2017/745 (EU-MDR).
[7] https://www.anmeldestelle.admin.ch/chem/en/home/themen/pflicht-hersteller/selbstkontrolle.html
[8] https://www.anmeldestelle.admin.ch/chem/en/home/themen/pflicht-hersteller/meldepflicht-zubereitungen.html
[9] https://www.anmeldestelle.admin.ch/chem/en/home/themen/pflichten-handel-abgabe-chemikalien.html
[10] Ordinance of 18 May 2005 on the Placing on the Market and Handling of Biocidal Products (Ordinance on Biocidal Products; OBP; SR 813.12)

Further information is available at https://www.anmeldestelle.admin.ch/chem/en/home/themen/pflicht-hersteller/zulassung-biozidprodukte.html.

6 Essential oils in or as cosmetics

Essential oils are principally used as ingredients in cosmetic products, including perfumes and soaps. There are no longer any maximum quantities. Essential oils may be used in cosmetics if a safety report is compiled in accordance with Article 4 of the FDHA Ordinance on Cosmetics (CosmO; SR 817.023.31) and provided they do not pose a risk to health (Art. 15 of the Foodstuffs Act (FSA; SR 817.0)). Certain oils or components are listed in the Annexes to European Regulation No 1223/2009 and may be used in cosmetics only in accordance with the conditions stated there[11].

Pure essential oils may be considered as cosmetic products in rare cases, provided they meet the definition of cosmetic products (Art. 53 of the Ordinance on Foodstuffs and Utility Articles (FSO; SR 817.02)), e.g. use as a concentrated mouthwash or as a bath additive with instructions for dilution in water.

References of any kind to disease curing, relieving or preventing effects of cosmetics (e.g. medicinal or therapeutic properties) are prohibited (Art. 47 para. 3 FSO).

Essential oils intended to be mixed with other components such as oils or lotions are to be classified as precursors or raw materials that are subject to the provisions of chemicals law.
Only essential oils used as ingredients in a “cosmetic kit” are considered to be covered by cosmetic products legislation, provided there is a link to the “recipe” (instructions and formulation) of the final cosmetic product (e.g. the same label or a clear reference to the original cosmetic kit).

The European Commission has published a borderline products manual[12] on the scope of Regulation (EC) No 1223/2009 on cosmetic products. The manual defines the products covered by cosmetics legislation and contains entries relating to essential oils. The manual is updated regularly and is very helpful in assessing individual cases.

Responsibility for legislating on these products lies with the FSVO’s Food and Nutrition Division, while the cantonal enforcement authorities (cantonal chemists) are responsible for inspections.

Further information is available at:
https://www.blv.admin.ch/blv/fr/home/gebrauchsgegenstaende/kosmetika-schmuck/kosmetika.html
http://www.kantonschemiker.ch

[11] See link: https://www.blv.admin.ch/blv/fr/home/gebrauchsgegenstaende/rechts-und-vollzugsgrundlagen/gesetzliche-anforderungen-kosmetika/geregelte-stoffe-kosmetische-mittel.html
[12] Borderline products manual on the scope of application of the Cosmetics Regulation (EC) No 1223/2009, revised version dated November 2023. Link: https://ec.europa.eu/docsroom/documents/58054

7 Essential oils in e-cigarettes

E-cigarettes including e-liquids are currently subject to food law and are considered as utility articles with mucous membrane contact. There is no authorisation or approval procedure for such products. However, the following legal requirements apply to essential oils in e-liquids:

- Mandatory labelling of potential hazards for consumers that cannot be identified without appropriate warnings (Art. 47 para. 1 FSO);
- References to disease curing, relieving or preventing effects (e.g. medicinal or therapeutic properties, disinfectant or anti-inflammatory action) are prohibited (Art. 47 para. 3 FSO);
- Substances may be supplied only in quantities that pose no risk to health (Art. 61 para. 1 FSO);
- The addition of substances conferring pharmacological effects on the products (e.g. nicotine) is prohibited (Art. 61 para. 2. FSO).

Compliance with these legal requirements is the distributor's responsibility and must be verified by means of self-supervision (Art. 26 FSA).

Based on the Cassis de Dijon principle, e-cigarettes from the EU or EEA may be placed on the Swiss market on condition that the products meet the technical requirements of an EU or EEA Member State and are lawfully in circulation in that state. These technical requirements also include appropriate labelling of the product. See Art. 16*a*, 16*b* and 16*e* of the Federal Act on Technical Barriers to Trade (TBA; SR 946.51).
Information on the requirements for e-cigarettes in the EU can be found in Directive 2014/40/EU.

Refill cartridges for e-cigarettes must also be labelled in accordance with chemicals legislation.

From 2024 it is expected that e-cigarettes and e-liquids will no longer fall under food law, but under the new Tobacco Products Act.

8 Essential oils in the area of foodstuffs

8.1 Essential oils as flavourings

The definition of food flavourings is based on Art. 2 para. 1 no. 25 FSO.
According to the FDHA Ordinance on Flavourings and Food Ingredients with Flavouring Properties in or on Foodstuffs (Flavourings Ordinance; SR 817.022.41), essential oils are to be assessed as flavouring extracts in accordance with Art. 2 let. c. A distinction must be drawn as to whether the oils are obtained from foodstuffs that are used as such, or from other plant substances. In the first case, the flavouring extracts can be used for flavouring with no further measures. In the second case, authorisation is required if the substance is not included in the positive list (Annex 3 to the Flavourings Ordinance).

Responsibility for legislating on these products lies with the FSVO's Food and Nutrition Division, while the cantonal enforcement authorities (cantonal chemists) are responsible for inspections.

8.2 Essential oils as novel foods

Foodstuffs that were not used for human consumption to a significant degree in either Switzerland or an EU Member State before 15 May 1997 must be authorised by the FSVO or by the European Commission. These are described as “novel foods” (Art. 15 FSO).
If essential oils in foods are not added for flavouring purposes, they must comply with the provisions on novel foods (Art. 15 to 19 FSO). Accordingly, if essential oils were not used as foodstuffs to a significant degree in Switzerland and/or an EU Member State before 15 May 1997, they require authorisation by the FSVO or the European Commission before being placed on the market.
Essential oils used as flavourings are not considered as novel foods (Art. 15 para. 2 let. b no. 3 FSO).

Responsibility for legislating on these products lies with the FSVO’s Food and Nutrition Division, while the cantonal enforcement authorities (cantonal chemists) are responsible for inspections.

8.3 Essential oils as or in food supplements

The use of essential oils in food supplements is not specifically regulated in Switzerland.

The provisions specific to food supplements are described in the FDHA Ordinance on Food Supplements (FoodSO; SR 817.022.14). Restrictions on the use of certain other substances in food supplements are contained in Annex 1 Part B FoodSO. Essential oils are not listed. Annex 1 Part B FoodSO is not exhaustive. Substances other than those listed in Annex 1 Part B may be contained in food supplements if the manufacturer, importer and distributor can demonstrate and document as part of their self-supervision that the substances are safe and fully compliant with food law requirements (see Information letter 2021/7.1: Self-supervision of non-regulated other substances in food supplements).

The correct classification and marketability assessment of a product containing essential oils must always take place on a case-by-case basis using all available relevant criteria. If essential oils are not used for flavouring purposes, questions arise regarding health protection, protection against deception, novel food status, pharmacological effect or delimitation from medicinal products. For further information on delimitation between foodstuffs and medicinal products, see the publication “Delimitation criteria for medicinal products / foodstuffs regarding products to be taken orally”. In addition, the product-specific requirements must be met in every case.

In general, products containing essential oils are not used to supplement a normal diet with substances having a nutritional or physiological effect, but are taken for therapeutic purposes. Consequently, they do not meet the requirements for food supplements.

Plants, parts of plants and preparations and substances derived therefrom that are listed in Annex 1 to the FDHA Ordinance on Foodstuffs of Vegetable Origin, Fungi and Table Salt (VFO; SR 817.022.17) may not be used as foodstuffs or added to foodstuffs in Switzerland.

In addition, foodstuffs advertising must not be misleading (Art. 18 FSA). Therapeutic indications and medicinal presentations are prohibited for foodstuffs (Art. 12 para. 2 let. c and d FSO). There are no permitted health claims for essential oils in foodstuffs (Art. 31 para. 2 with Annex 14 of the FDHA Ordinance on Information on Foodstuffs (FoodIO; SR 817.022.16)).

Responsibility for legislating on these products lies with the FSVO's Food and Nutrition Division, while the cantonal enforcement authorities (cantonal chemists) are responsible for inspections.