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. The classification of essential oils and products containing them prompts many 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 therefore lists the main criteria to be taken into account when classifying such products[1].

It aims 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, in electronic cigarettes and cosmetics, or in foodstuffs, and be marketed in Switzerland only if they meet the requirements set out below.

[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

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 the human or animal body, 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. Dosage forms and methods of application that are associated with increased absorption of essential oils into the body and could therefore produce potentially significant pharmacological effects are also classed as medicinal products. This includes applications that are inserted into the body (e.g.rectal and vaginal suppositories) or held to the mouth and nose for inhalation (nasal inhalers and other inhalation aids). 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. The distributor 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 person in charge 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).

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[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, link: https://www.kantonsapotheker.ch/de/leitlinien-/-positionspapiere-/-listen/kav-positionspapiere

If multiple classification rules apply to a product, the strictest rule applies in each case, resulting in the product being classified in 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.

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 the essential oils it contains 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 documented 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 the supplier of Group 2 products must have training and expertise 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/de/atherische-ole
Note: It happens again and again that essential oils are placed on the market improperly under chemicals legislation, even though they are 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. This is because their purity, efficacy and tolerability do not necessarily meet the requirements and have not been tested.

[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

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).

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 mainly 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, FoodA, SR 817.0). Some 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, FUAO, 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 FUAO).

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, in which the products covered by cosmetics legislation are defined. It contains entries about essential oils. The manual is updated regularly and is very helpful in assessing individual cases.

[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)
[11] See link: https://www.blv.admin.ch/blv/de/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 2024. Link: https://ec.europa.eu/docsroom/documents/58054

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/de/home/gebrauchsgegenstaende/kosmetika-schmuck/kosmetika.html
http://www.kantonschemiker.ch

7 Essential oils in e-cigarettes

E-cigarettes, including e-cigarette liquids with and without nicotine (e-liquids), have been subject to the Tobacco Products Act (TabPA) since 1.10.2024[13]. There is no authorisation or approval procedure for such products. As a general rule, essential oils should not be inhaled via e-liquids, so as to avoid respiratory impairment and possible long-term damage to the lungs. The use of certain oils such as camphor oil is explicitly prohibited under Art. 7 para. 1 and Annex 1 TabPA.
In general, e-liquids are subject to the following legal requirements:

- The presentation must not give rise to any misconceptions as to health effects – protection against deception (Art. 5 TabPA).
- Ingredients must not directly endanger health, significantly increase toxicity or have a psychotropic effect. Liquids must also be of high purity and, with the exception of nicotine, pose no risks to health (Art. 6 TabPA).
- Liquids must be labelled accordingly and bear warnings (Art. 10 and 14 para. 1 let. d and e TabPA).
- Compliance with these legal requirements is the distributor's responsibility and must be ensured by means of self-regulation (Art. 25 TabPA).
- The Ordinance on Tobacco Products (TabPO)[14] regulates further details, e.g. concerning self-regulation (Art. 21 TabPO).

Refillable containers of liquid must additionally meet certain requirements of chemicals legislation (Art. 24 TabPO). Extended reporting requirements also apply, e.g. the unique formula identifier (UFI) must be reported for emergency information in accordance with Art. 15*a* ChemO (Art. 27 TabPO).

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 FUAO.
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 procedures. In the second case, they

[13] SR **818.32**
[14] SR **818.321**

must be included in the positive list in Annex 3 as part of the legislative process if they are not already listed there.

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 classed as novel foods (Art. 15 FUAO).
If essential oils in foods are not added for flavouring purposes, they must comply with the provisions on novel foods (Art. 15 to 19 FUAO). 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 by the European Commission before being placed on the market.
If essential oils are used as flavourings, they are not considered as novel foods (Art. 15 para. 2 let. b no. 3 FUAO).

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 dietary supplements

The use of essential oils in dietary supplements (DS) is not specifically regulated in Switzerland.

The provisions specific to dietary supplements are described in the FDHA Ordinance on Dietary Supplements (DietSO, SR 817.022.14). Restrictions on the use of certain other substances in dietary supplements are contained in Annex 1 Part B DietSO. Essential oils are not listed. Annex 1 Part B DietSO is not exhaustive. Other substances may be included in dietary supplements. As part of their self-regulation, the manufacturer, importer and distributor must demonstrate and document that the substances are safe and fully compliant with food law requirements (see Information notice 2021/7.1: Self-regulation in the case of other non-regulated substances in dietary supplements).

Correct classification and assessment of the marketability of a product containing essential oils must always take place on a case-by-case basis using all available criteria relevant to the assessment. If essential oils are not used for flavouring purposes, questions arise regarding consumer health, protection against deception, novel food status, pharmacological action or delimitation compared with 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. They do not therefore meet the requirements for dietary supplements.

Plants and parts of plants as well as preparations and substances derived from them 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 FoodA). Therapeutic indications and medicinal presentations are prohibited for foodstuffs (Art. 12 para. 2 let. c and d FUAO). No health claims are authorised for essential oils in foodstuffs (Art. 31 para. 2 in relation 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.

9 Change history

Version	Date	Description
3.0	15.12.2025	Small update
2.0	02.04.2025	Adaptation in line with new tobacco products legislation
1.0	11.06.24	First version