Schweizerische Eidgenossenschaft
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Federal Office of Public Health (FOPH)

swissmedic

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Regulations on disinfectants in Switzerland

Information sheet

In Switzerland, there are various categories of disinfectants that are distinguished by type of application. The legal requirements vary by application.

In order to place a disinfectant on the Swiss market, its product category must first be assigned on the basis of the planned application (intended use). Thereafter, all of the corresponding legal requirements must be met.

Typical examples include:

Intended use	Product category	Legal references
Wound and skin disinfection for patients	Medicinal product	TPA[1], TPLRO[2]
Disinfection of medical devices	Medical device	TPA, MedDO[3]
Hand and surface disinfection	Biocidal product	ChemA[4], OBP[5]

1 Medicinal products

Responsibility: Swissmedic
Disinfectants have to be authorised as medicinal products if they are intended for use in preventing or healing diseases (infections) by application to the patient's skin/mucous membranes (including for disinfecting wounds) and in the case of use in patients prior to surgical interventions (preoperative skin disinfection, antiseptic body wash).

The licensing and market surveillance of these disinfectants as medicinal products are within the scope of responsibility of **Swissmedic**, the Swiss Agency for Therapeutic Products.

2 Medical devices

Responsibility: Swissmedic
Disinfectants that are specifically intended for the disinfection of medical devices are also classified as medical devices (Art. 3 para. 2 letter b MedDO).

Devices for disinfecting medical devices are assigned to Class IIa unless they are disinfectants or washer disinfectors that are used specifically for disinfecting invasive devices as ready-to-use, disinfected devices; in this case, they are assigned to Class IIb.

Devices for disinfecting contact lenses are also considered medical devices and are assigned to Class IIb.

Disinfectants that are considered medical devices must undergo a conformity assessment procedure and must then be marked with the conformity marking (CE or MD mark) and the identification number of the notified body.

[1] TPA: Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act; SR 812.21)
[2] TPLRO: Ordinance of the Swiss Agency for Therapeutic Products on the Licensing Requirements for Therapeutic Products (Therapeutic Products Licensing Requirements Ordinance, SR 812.212.22)
[3] MedDO: Medical Devices Ordinance (SR 812.213)
[4] ChemA: Federal Act on Protection against Dangerous Substances and Preparations (Chemicals Act, SR 813.1)
[5] OBP: Ordinance on the Placing on the Market and Handling of Biocidal Products (Ordinance on Biocidal Products, SR 813.12)

Medical devices are subject to market surveillance by **Swissmedic**.

3 Biocidal products

Responsibility: Federal Office of Public Health (FOPH)
All other disinfectants, including those used in healthcare institutions and laboratories, e.g. to disinfect hands for hygiene purposes (such as hand sanitisers containing ethyl alcohol) / prior to surgery (on healthy intact skin) or for disinfecting surfaces have been governed by the Chemicals Act since 1 August 2005 and require authorisation in accordance with Art. 7 of the Ordinance on the Placing on the Market and Handling of Biocidal Products. Marketing authorisation applications for biocidal products must be submitted to the Notification Authority for Chemicals, **Federal Office of Public Health**, 3003 Bern (see also https://www.anmeldestelle.admin.ch/chem/en/home/themen/pflicht-hersteller/zulassung-biozidprodukte.html).

Note: Products used as biocides must be licensed as biocidal products. Therefore, products intended for hygiene as hand sanitisers cannot be marketed as formula-related medicinal products.

4 Products with multiple applications

Regulating a disinfectant under specific legislation is important from the standpoint of health enforcement authorities, because different requirements are in effect for placing products on the market and market surveillance, depending on the applicable laws. Compliance with these requirements is, in turn, monitored by different responsible authorities. Correct categorisation is the only way to ensure that users and consumers are protected from insufficiently certified products.

As a result, a disinfectant with multiple applications must be scrutinised with regard to the relevant enforcement issues and legal compliance with the labelling requirements for multiple labelling.

4.1 Dual use as a medicinal product and a medical device

According to Swiss therapeutic products legislation, a product qualifies as either a medicinal product or a medical device, depending on its principal intended action (Art. 4 para. 1 letters a and b TPA). Therefore, dual use of a disinfectant as a medicinal product and a medical device is not permitted.

4.2 Dual use as a medicinal product and a biocide

Because information and illustrations on human medicinal products are permitted only if they relate directly to the use of the medicinal product (Art. 12 para. 1 in conjunction with Annex 1 ch. 1 para. 8 TPLRO), the mere implementation of legally compliant multiple labelling as a medicinal product and a biocide is essentially prohibited.

4.3 Dual use as a biocide and a medical device

A disinfectant that is to be placed on the market for dual use as a biocide and a medical device is not categorically excluded under the two regulations (OBP, MedDO). However, it requires the completion of a conformity assessment procedure under the medical devices regulations and official marketing authorisation as a biocidal product by the FOPH.
In this case the products, including their labelling, must meet all of the relevant requirements that apply to medical devices and biocides. If these products meet the requirements of both

ordinances, dual labelling is possible. The product labelling must clearly and unambiguously provide the required information and instructions for use as a medical device and as a biocide.