



Office for Product
Safety & Standards

Placing hand cleaning and sanitising products on the UK market

Guidance for Businesses, Version 3

May 2020



Placing hand cleaning and sanitising products (such as liquids, gels and soaps) on the UK market

All hand cleaning and sanitising products are regulated in the UK

This guidance is intended for businesses that are new to the manufacture or import of hand cleaning and sanitising products. If you are manufacturing or importing hand cleaning or sanitising products you must comply with the regulations that apply to your product. This ensures that products are safe to use and effective. The specific legislation that applies depends on the products' intended use, function, composition and how they are described and marketed.

Hand sanitising products generally fall into one of three categories:

1. Products primarily used to clean, protect, and condition skin or any other cosmetic enhancement while providing a secondary antimicrobial effect, such as a liquid soap, solid soap bars, sun lotion and moisturising hand creams. These are classed as a **cosmetic product**.
2. Products primarily claiming to kill germs, disinfect or sanitise using an active antimicrobial ingredient such as the hand sanitisers used in hospitals. These are classed as a **biocide**.
3. Products specifically used as surgical scrubs for use in operating theatres and products which make claims to treat and / or prevent infection associated with specifically named pathogens. These are classed as **medicines**.

If a product claims to prevent infection against specific viruses, such as COVID-19 or other named pathogens or illnesses, it will be classed as a medicine.

There are borderline cases for each of these categories and determination of product category needs to be made on a case by case basis. If you are unsure which category your product falls in to, please seek help from the relevant regulator.

Where do I find out more?

If a product is a **Cosmetic Product** the regulations that apply are the Cosmetic Product Regulations. These are regulated through your local authority, by Trading Standards services in Great Britain and Environmental Health services in Northern Ireland. Guidance on the requirements for these products is available here:

<https://www.businesscompanion.info/en/quick-guides/product-safety/cosmetic-products>.

Your local authority can provide additional advice. You can obtain details of your local Trading Standards service here: <https://www.gov.uk/find-local-trading-standards-office> or your local Environmental Health service in Northern Ireland here:

<https://www.nidirect.gov.uk/articles/find-your-local-council>

If a product is a **Biocide** there are multiple regulations that may apply. These are regulated by the Health and Safety Executive. For guidance contact the Health and Safety Executive (HSE) (biocidesenquiries@hse.gov.uk).

The HSE has issued a derogation, in the short term, from product authorisation for hand sanitiser containing propan-2-ol. Products containing propan-2-ol will not be required to obtain a product authorisation if they meet the relevant [WHO-specified formulation II](#). However, manufacturers must contact the HSE via biocidesenquiry@HSE.gov.uk

[WHO-specified formulation I](#) does not require a product authorisation. During this exceptional time HSE will take a pragmatic and proportionate approach to regulatory requirements and inspectors will take a sensible and proportionate approach if they come across sanitisers that are not strictly in line with normal BPR supply chain requirements under Article 95, where manufacturers have taken all reasonable steps to source ingredients in such a way that they are compliant with Article 95 requirements.

In making commercial decisions, manufacturers need to be mindful of maintaining high levels of safety and efficacy of the products they make available to the public and others.

[Full HSE derogation statement and further advice](#)

If the product is a **Medicine**, these are regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA) and guidance is available here:

<https://www.gov.uk/guidance/decide-if-your-product-is-a-medicine-or-a-medical-device> and <https://www.gov.uk/topic/medicines-medical-devices-blood/manufacturing-wholesaling-importing-exporting-medicines>.

There is also an online potential medicines advice request form here:

https://info.mhra.gov.uk/forms/borderline_advice.aspx

In addition to the above regulations, other regulations apply where products are sold pre-packaged, relating to weights and measures and packaging requirements. These are regulated through your local Trading Standards service.

Guidance for England, Wales and Scotland is available here:

<https://www.businesscompanion.info/en/quick-guides/miscellaneous/the-composition-and-use-of-packaging> and

<https://www.businesscompanion.info/en/quick-guides/weights-and-measures/packaged-goods-average-quantity>

Guidance for Northern Ireland is available here:

<https://www.nibusinessinfo.co.uk/content/packaging-and-packaging-waste-management> and

<https://www.nibusinessinfo.co.uk/content/weights-and-measures>

If you do not currently have appropriate equipment to comply with the packaging and packaged goods regulations, you should liaise with your local Trading Standards service who should be able to advise you.

Further information

The Department for Health and Social Care (DHSC) continue to update its website with guidance for new suppliers and manufacturers of hand sanitiser to protect NHS health workers. Its website includes a specification for hand wash:

<https://www.gov.uk/government/publications/technical-specifications-for-personal-protective-equipment-ppe>

Where new suppliers have a product that meets these requirements, DHSC welcome offers of support through [this online form](#).

BSI, in its role as the UK's National Standards Body, is working with Government to provide expert, best practice information. As a result, they have made accessible relevant standards to support efforts in tackling COVID-19.

Many hand sanitising products contain highly flammable alcohol-based ingredients. Businesses need to consider the added risks of storage and processing these materials.

The main government and Public Health England page for advice on Covid-19 is at <https://www.gov.uk/government/topical-events/coronavirus-covid-19-uk-government-response>.

NHS guidance on Covid-19 is at <https://www.nhs.uk/conditions/coronavirus-covid-19/>

It is important that everyone uses biocidal products responsibly, correctly and effectively. The HSE website, <https://www.hse.gov.uk/biocides/using.htm>, offers information and advice for users of biocidal products.

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