Coronavirus (COVID-19) - manufacture and supply of hand sanitisers

Manufacturers and suppliers of hand sanitisers must comply with the law. This may mean the Health and Safety Executive (HSE) needs to authorise your product.

Check which regulations apply to your product

All hand cleaning and sanitising products (such as liquids, gels and soaps) are regulated in the UK.

If you manufacture or import hand sanitising products you must comply with the regulations relevant to each product in your range.

Hand sanitising products fall into one of three regulatory groups. The group depends on each product's intended use, function, composition or how the product is described:

- Products primarily used to clean and/or moisturise skin while providing a secondary antimicrobial effect are classed as a cosmetic. This group includes liquid soap and solid soap bars.

  The regulations that apply here are the Cosmetic Product Regulations (www.businesscompanion.info/en/quick-guides/product-safety/cosmetic-products).

  Contact your local Trading Standards office (www.gov.uk/find-local-trading-standards-office) for information and advice.

- Products which claim to treat or prevent infections associated with specifically named pathogens (such as COVID-19) are classed as medicines. Other products in this group include those used as surgical scrubs in operating theatres.

  Medicines need marketing authorisations (www.gov.uk/topic/medicines-medical-devices-blood/marketing-authorisations-variations-licensing).

Contact the Medicines and Healthcare products Regulatory Agency (MHRA) at borderline_medicine@mhra.gov.uk for information and advice.

- Products that primarily claim to kill germs, disinfect, or sanitise using an active antimicrobial ingredient are classed as biocides. This group includes hand sanitisers.

  General hand sanitiser products cannot name specific pathogens (such as COVID-19). This guidance gives information on the regulatory requirements for hand sanitisers under biocides.

  Contact HSE's biocides helpdesk at biocidesenquiries@hse.gov.uk for further advice.

General legal requirements for biocidal hand sanitiser products

Classification, labelling and packaging of substances and mixtures (CLP)

If you supply biocidal hand sanitiser products you must comply with the law on classification, labelling and packaging of substances and mixtures (CLP) (www.hse.gov.uk/chemical-classification/index.htm).

Labels must not mislead consumers about risks from the product to human health, animal health, the environment, or the product's efficacy.

Labels must also not use the following or any similar terms:

- low-risk biocidal product
- non-toxic
- harmless
- natural
- environmentally friendly
- animal friendly

Labels cannot include any medicinal claims.

Advertising

Advertisements for biocidal hand sanitisers must not mislead consumers about risks from the product to human health, animal health, the environment, or the product's efficacy.

They must also not use the following or any similar terms:

- low-risk biocidal product
- non-toxic
- harmless
- natural
- environmentally friendly
- animal friendly

Advertisements cannot include any medicinal claims.

Record keeping

You must keep records of the quantity and safety of the biocidal hand sanitiser products you supply in the UK (www.hse.gov.uk/biocides/recording-keeping-reporting.htm).

REACH

If you import biocidal hand sanitiser products from outside Great Britain (outside the EU if you're in Northern Ireland) then the REACH Regulation (1907/2006) as amended by UK REACH Regulations SI 2019/758 (UK REACH) (or the EU REACH Regulation (1907/2006) with respect to Northern Ireland) may apply to the individual non-active substances or ingredients present in the product.

UK REACH (or EU REACH if you're in Northern Ireland) has a registration duty which applies to the manufacture or import of chemical substances into Great Britain (or the EU if you're in Northern Ireland) in quantities of 1 tonne or more a year.

In the case of a mixture, it is the individual substances or ingredients in the mixture that are subject to the registration duty and not the mixture itself.

If you import hand sanitiser products, then any UK REACH (or EU REACH if you're in Northern Ireland) registration duties fall to you as the GB-based (or EU-based if you're in Northern Ireland) importer in the supply chain.

You must decide if any of the individual non-active substances or ingredients in the hand sanitiser trigger the registration threshold of 1 tonne or more a year.

You must also decide if any of the substances are not subject to registration under UK REACH (or EU REACH if you're in Northern Ireland). Some substances - such as water for example - are exempt.

For more help with REACH registration, email the REACH Helpdesk at ukreach.clp@hse.gov.uk.

Article 95

Article 95 of the Biocidal Products Regulation (BPR) says that the active substance in a biocidal product must be sourced from one of the suppliers included on a specific list. This is known as the Article 95 list.

There are separate Article 95 lists for Great Britain and Northern Ireland:

• GB Article 95 list in Great Britain (www.hse.gov.uk/biocides/uk-article-95-list.htm)

• EU Article 95 list in Northern Ireland (https://echa.europa.eu/information-on-chemicals/active-substance-suppliers).

This does not mean you have to buy direct from an Article 95 supplier. It does mean you must be able to trace supply back to one of these companies via proper records such as invoices.

• If you are supplying hand sanitisers in Great Britain, you must be able to trace your supply to a supplier on the GB list.

• If you are supplying hand sanitisers in Northern Ireland, you must be able to trace your supply to a supplier on the EU list.

• If you are supplying hand sanitisers in both Great Britain and Northern Ireland, you must be able to trace your supply to either:

- a single supplier that appears on both the GB and EU lists, or
- one supplier on the GB list (for the GB market) and one supplier on the EU list (for the Northern Ireland market).

During this exceptional time of the COVID-19 pandemic, manufacturers may need to find alternative suppliers of raw ingredients to supplement those obtained via regular supply chains.

HSE's primary concern is that safe and effective biocidal hand sanitisers are available to help protect people in the UK during the pandemic.

HSE expects product manufacturers to take all reasonable steps to source ingredients to be compliant with Article 95 obligations.

However, HSE inspectors will take a sensible and proportionate approach if they come across hand sanitisers that are not strictly in line with normal BPR supply chain requirements under Article 95. This is in recognition of the continuing urgent need for safe and effective products.

If you have to use a source that is not on the relevant Article 95 list(s), keep a record of the actions you took to source the active substance from companies on the relevant Article 95 list(s). You may be asked to justify your decision in the future.

As an example, if you have emailed suppliers on the relevant Article 95 list(s) but they were unable to supply you with the active substance, your emails could show you tried to source Article 95 compliant ingredients.

You should also keep a note of any phone calls you make and follow up by email.

Manufacturers need to be mindful of maintaining high levels of safety and efficacy of the products they supply.

Testing

You are responsible for making sure the products you supply are effective and meet any necessary testing standards. This also includes making sure any claims for the products can be verified by supporting data.

British Standard BS EN 14885 outlines standard efficacy testing for disinfectant products. EN 14885 provides a list of standards for different types of products.

Note that EN 14885 does not provide detailed test methods but rather a list of other standards you should use, for example EN 1500, EN 1276 and EN 14476.

If your product requires BPR product authorisation the BPR efficacy guidance (https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation), (volume II, parts B+C) provides in-depth information on testing.

Appendices 3 and 4 of the efficacy guidance contain a useful summary of the sort of testing normally expected for disinfectant products.

In some cases, there may not be a test method that exactly matches how your product should be applied. You will need to consider if an existing method could be appropriately adapted, or whether there is a suitable alternative testing strategy.

You may need to consult a specialist such as a test house to discuss your requirements. You will need to be able to demonstrate that any efficacy claims can be substantiated.

Other requirements

Organisations such as the NHS may have specific requirements for hand sanitiser products for use in the health care system. You should approach these organisations directly to check their requirements in advance.

The Department of Health and Social Care (DHSC) has published details of specifications for hand sanitisers and hand washes for use in the healthcare system (www.gov.uk/government/publications/technical-specifications-for-personal-protective-equipment-ppe).

Other government departments such as the Department of Education (DfE) may also have requirements or recommendations. There's more about this in the coronavirus (COVID-19) guidance on www.GOV.UK/coronavirus.

The general product safety regulations (www.gov.uk/guidance/product-safety-advice-for-businesses#general-product-safety-regulations) says manufacturers must make sure that the products they supply are safe and effective. Manufacturers must also be sure the grade of chemicals they use does not impact on this.

Manufacturers should be aware of the specification and impurity profile of the chemicals they use. This is particularly important with hazardous impurities such as methanol.

You should also provide information on the products to the National Poisons Information Service (www.hse.gov.uk/biocides/informing-npis.htm).

Any workplace producing, using or storing hand sanitiser products must also comply with the relevant health and safety regulations.

Specific legal requirements for biocidal hand sanitiser products

Additional requirements may apply to your hand sanitiser product depending on the active substance(s) it contains.

To help you identify the specific legal requirements that apply to your hand sanitiser product, HSE has put together a list of the known biocidal active substances relevant for hand sanitisers.

You can read about these requirements at www.hse.gov.uk/coronavirus/assets/docs/hand-sanitiser-active-substance.pdf.

The active substances are grouped by the specific requirements that apply to them. This includes whether the products that contain them need to be authorised.

The document describes the action you need to take for each group before you supply your hand sanitiser in the UK. If your hand sanitiser contains multiple active substances, you will need to check the actions relevant to each active substance and comply with the appropriate requirements.

If any of your active substances are not listed in this document, your hand sanitiser cannot be supplied or used in the UK.

The regulatory status of the active substances in the document may change. This means the requirements that apply to your hand sanitiser product may change. You should check the document regularly to make sure your product remains compliant.

Further information

For information about health and safety, or to report inconsistencies or inaccuracies in this guidance, visit www.hse.gov.uk.

You can view HSE guidance online and order priced publications from the website. HSE priced publications are also available from bookshops.

You can find this document at: www.hse.gov.uk/coronavirus/assets/docs/hand-sanitiser-manufacture-supply-coronavirus.pdf

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