

Coronavirus (COVID-19) - manufacture and supply of surface disinfectants

Manufacturers and suppliers of surface disinfectants must comply with the law. This may mean HSE needs to authorise your product.

Disinfectants for use on surfaces are regulated as biocidal products in the UK under the Biocidal Products Regulation (BPR).

Surface disinfectants may fall under one or more of the following BPR product types depending on where they're used:

- product type 2 for surfaces in the home, offices, clinical settings and so on
- product type 3 for surfaces including pet beds and cages and some uses directly on animal skin
- product type 4 for surfaces in food and feed areas such as kitchen worktops

It is important you identify the relevant BPR product type for your product. There are more detailed descriptions at www.hse.gov.uk/biocides/regulated/regulated-2.htm.

If you supply a disinfectant specifically for disinfecting medical devices, your product may be treated as an accessory to the medical device and regulated under medicines legislation.

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

If the MHRA says your product is not regulated under their legislation, BPR then applies to the product.

General legal requirements for surface disinfectant products

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

If you are supplying surface disinfectant 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 surface disinfectant products 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 (www.hse.gov.uk/biocides/recording-keeping-reporting.htm) of the quantity and safety of the surface disinfectant products you supply in the UK.

REACH

If you import surface disinfectant products from outside Great Britain (or the EU if you're in Northern Ireland), the REACH Regulation (1907/2006) as amended by UK REACH Regulations SI 2019/758 (UK REACH) (or the EU REACH Regulation (1907/2006) if you're in 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 surface disinfectant 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 your product 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 surface disinfectants in Great Britain, you must be able to trace your supply to a supplier on the GB list.
- If you are supplying surface disinfectants in Northern Ireland, you must be able to trace your supply to a supplier on the EU list.
- If you are supplying surface disinfectants 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).

HSE is currently taking a pragmatic approach to BPR Article 95 supply chain requirements for **hand sanitiser products** during the COVID-19 pandemic. This approach does not apply to **surface disinfectants**.

Testing

You are responsible for making sure the products you supply are effective and meet any necessary testing standards. This 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. It provides a list of other standards that you should use, for example EN 1650, 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 disinfectant products for use in the health care system. You should approach these organisations directly to check their requirements in advance.

Other government departments may have their own 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) require manufacturers to make sure the products they supply are safe and effective. This means they must be sure that 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 surface disinfectant products must also comply with the relevant health and safety regulations.

Specific legal requirements for surface disinfectant products

HSE has put together a series of lists of the known biocidal active substances that are relevant for the different types of surface disinfectants in the UK.

These lists will help you identify the legal requirements that apply to your surface disinfectant product:

- Product type 2 for use on surfaces around the home and in offices and clinical settings: www.hse.gov.uk/coronavirus/assets/docs/product-type-2-active-substances.pdf
- Product type 3 for use on surfaces including pet beds and cages and for some uses directly on animal skin: www.hse.gov.uk/coronavirus/assets/docs/product-type-3-active-substances.pdf
- Product type 4 for use on surfaces in food and feed areas such as kitchen worktops: www.hse.gov.uk/coronavirus/assets/docs/product-type-4-active-substances.pdf

The active substances are grouped by the specific requirements that apply to them within each document. The document describes the action you need to take for each group before you supply your surface disinfectant in the UK.

If your product contains multiple active substances you will need to check the actions relevant to each active substance and comply with the appropriate requirements.

If the use of your product falls into more than one of these three product types, you will need to check the actions relevant to each active substance in each relevant product type and comply with the appropriate requirements.

If any of your active substances are not listed in these documents, you cannot supply or use your surface disinfectant in the UK.

The regulatory status of the active substances in the documents may change. This means the requirements that apply to your surface disinfectant product may change. You should check the documents 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 our website. HSE priced publications are also available from bookshops.

This document is available at: www.hse.gov.uk/coronavirus/assets/docs/surface-disinfectant-manufacture-supply-coronavirus.pdf.

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