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

Manufacturers and suppliers of surface disinfectants must comply with the relevant laws. This may mean your product needs to be authorised by HSE.

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 are intended to be used:

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

It is important you identify the relevant BPR product type for the use of your product – more detailed descriptions are available at [www.hse.gov.uk/biocides/basics.htm](http://www.hse.gov.uk/biocides/basics.htm).

If you supply a disinfectant specifically intended for use to disinfect medical devices, that disinfectant may be treated as an accessory to the medical device and be regulated under medicines legislation. Contact the Medicines and Healthcare products Regulatory Agency (MHRA) at [devices.regulatory@mhra.gov.uk](mailto:devices.regulatory@mhra.gov.uk) for information and advice. If the MHRA confirm it would be not be regulated under their legislation, BPR would then apply 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 relevant legislation on Classification, Labelling and Packaging of substances and Mixtures (CLP) ([www.hse.gov.uk/chemical-classification/index.htm](http://www.hse.gov.uk/chemical-classification/index.htm)).
Labels must not be misleading in respect of the risks from the product to human health, animal health or the environment, or in relation to its efficacy.

Labels must not mention the terms 'low-risk biocidal product', 'non-toxic', 'harmless', 'natural', 'environmentally friendly', 'animal friendly' or similar indications, or include any medicinal claims.

Advertising

Adverts for surface disinfectant products must not be misleading in respect of the risks from the product to human health, animal health or the environment, or in relation to its efficacy.

Adverts must not mention the terms 'low-risk biocidal product', 'non-toxic', 'harmless', 'natural', 'environmentally friendly', 'animal friendly' or similar indications, or include any medicinal claims.

Record keeping

You must keep records [www.hse.gov.uk/biocides/eu-bpr/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 with respect to 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) with respect to Northern Ireland) may apply to the individual non-active substances/ingredients present in the product.

UK REACH (or EU REACH with respect to Northern Ireland) has a registration duty which applies to those that manufacture or import chemical substances into Great Britain (or the EU with respect to Northern Ireland) in a quantity of 1 tonne per year or more. In the case of a mixture, it is the individual substances/ingredients within the mixture that are subject to the registration duty, and not the mixture itself.

If you do import surface disinfectant products, then any UK REACH (or EU REACH with respect to Northern Ireland) registration duties would fall to you as the GB-based (or EU-based with respect to Northern Ireland) importer in the supply chain. You would need to determine if each of the individual non-active substances/ingredients within the surface disinfectant trigger the registration threshold of 1 tonne per year or more.

You will also need to decide if any of the substances are not subject to registration under UK REACH (or EU REACH with respect to Northern Ireland), for example some substances, such as water, are exempt. If you require any further help on REACH registration, email the REACH Helpdesk at ukreach.clp@hse.gov.uk.
Article 95

Article 95 of the Biocidal Products Regulation (BPR) requires that the active substance in a biocidal product has to be sourced from one of the suppliers included on a specific list – known as the Article 95 list. There are separate lists for Great Britain and Northern Ireland:

- The GB Article 95 List in Great Britain ([www.hse.gov.uk/biocides/uk-article-95-list.htm](http://www.hse.gov.uk/biocides/uk-article-95-list.htm))
- The EU Article 95 List in Northern Ireland ([https://echa.europa.eu/information-on-chemicals/active-substance-suppliers](https://echa.europa.eu/information-on-chemicals/active-substance-suppliers)).

This does not mean you have to purchase directly from an Article 95 supplier, but 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 NI market).

**Please note** that the measures implemented by HSE to adopt a pragmatic and proportionate approach to the regulatory requirements that relate to BPR Article 95 supply chain obligations during the coronavirus pandemic are applicable only to hand sanitiser products and not surface disinfectants.

Testing

It remains your responsibility to ensure the products you supply are suitably effective, including meeting any necessary testing standards. This also includes ensuring 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. Please note, EN 14885 does not provide detailed test methods but rather a list of other standards that should be used, eg EN 1650, EN 1276, EN 14476 etc.

If your product requires BPR product authorisation (the information under the heading ‘Specific legal requirements for surface disinfectant products’ will help you determine this), the BPR efficacy guidance – [https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation](https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation) Volume II, Parts B+C also 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 is intended to 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. However, you will need to be able to demonstrate that any efficacy claims can be substantiated.

Other requirements

Organisations like the NHS may have specific requirements for disinfectant products which are intended to be used in the health care system. It is advisable to approach these organisations directly to check their requirements in advance. Other government departments may also have their own requirements or recommendations. See the coronavirus (COVID-19) guidance on GOV.UK/coronavirus.

The general product safety regulations (www.gov.uk/guidance/product-safety-advice-for-businesses#general-product-safety-regulations) requires manufacturers to ensure that the products they make available to the public and others are safe and effective. Therefore, they must ensure that the grade of chemicals they use does not impact on this. Manufacturers should therefore have an awareness of the specification and impurity profile of the chemicals they use, particularly regarding the presence of any hazardous substances such as methanol.

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

Any workplace producing or using or storing surface disinfectant products must also comply with relevant health and safety regulations.

Specific legal requirements for surface disinfectant products

To help you identify the specific legal requirements that apply to your surface disinfectant product, 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:

- Product type 2 for uses on surfaces around the home, offices, clinical settings etc: www.hse.gov.uk/coronavirus/assets/docs/product-type-2-active-substances.pdf
- Product type 3 for use on surfaces such as pet beds, cages etc and 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
Within each document, the active substances are grouped by the specific requirements that apply to them, eg whether the products that contain them need to be authorised or not. For each group, the document describes the action you need to take **before** you supply your surface disinfectant 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 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, your surface disinfectant cannot be supplied or used in the UK.**

The regulatory status of the active substances in the documents may be subject to change, meaning that the requirements that apply to your surface disinfectant product may change. You should check the documents regularly to ensure 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.

This document is available at:

© Crown copyright If you wish to reuse this information visit www.hse.gov.uk/copyright.htm for details.

First published 05/20.
Health and Safety Executive 04/21
Published by the Health and Safety Executive 11/20