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 Product Regulations (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 and/or product type 4 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.

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/eu-bpr/product-types.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 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).

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 the EU, the REACH Regulation (1907/2006) **may** apply to the individual non-active substances/ingredients present in the product.

REACH has a registration duty which applies to those that manufacture or import chemical substances into the EU 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 REACH registration duties would fall to you as the EU-based 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 REACH, for example some substances, such as water, are exempt. Further information about exemptions can be found in our short information leaflet (http://www.hse.gov.uk/reach/resources/exemptions.pdf).

For information on registration there is a wide range on the ECHA website; a good place to start could be the webpage ‘Your registration obligations’ (https://echa.europa.eu/support/registration/your-registration-

obligations). If you require any further help on REACH registration, email the REACH Helpdesk at ukreachca@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 (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. The list of Article 95 suppliers can be found on the European Chemicals Agency (ECHA) website (https://echa.europa.eu/information-on-chemicals/active-substance-suppliers) .

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 outbreak are applicable only to hand sanitiser products and not surface disinfectants.

Testing

It remains your responsibility to ensure the products you supply are suitably efficacious, 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 1500, EN 1276, etc.

If your product requires BPR product authorisation (the information under the heading ‘Other requirements’ will help you determine this), the BPR efficacy guidance – 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.

Organisations like the NHS may also 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 requirements

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 (https://echa.europa.eu/information-on-chemicals/active-substance-suppliers).

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

Specific regulatory requirements for surface disinfectant products

There may be additional UK regulatory requirements that apply to surface disinfectant products depending on the approval status of the active substance(s) under BPR for use in the relevant product type(s) – 2, 3 and/or 4.

You should check the database on the European Chemicals Agency (ECHA) website (https://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances) for details on the approval status of all biocidal active substances under BPR. You can filter the database by the relevant product type(s) (2, 3 and/or 4) to see all of the relevant active substances for your surface disinfectant products, or search for a specific active substance – we recommend searching by CAS or EC number for the most accurate result.

You will need to check for an ‘Approval start date’ **and** click on the blue eye symbol to check the ‘Approval/Assessment status’ **and** ‘Regulatory Process’.

Once you know **all** of these pieces of information for all of the active substances in your surface disinfectant, check the table below for what you need to do.

Please note that the Critical Situation Permit issued by HSE under Article 55(1) of BPR for the WHO-specified formulation based on propan-2-ol is only available for hand sanitiser products and is not applicable to surface disinfectants.

Scenario	Approval/ Assessment status	Approval start date	Regulatory Process	What you need to do
1	All **approved**	All in the past	N/A	Apply for product authorisation –details below the table
2	All **approved**	Some in the future	One or more with approval dates in the future are **new active substances**	Apply for product authorisation –details below the table
3	All **approved**	Some in the future	Those with approval dates in the future are **review programme substances**	No need to apply for product authorisation – details below the table
4	All **initial application for approval in progress**	N/A	All **review programme substances**	No need to apply for product authorisation – details below the table
5	Some **approved**, some **initial application for approval in progress**	N/A	All **review programme substances**	No need to apply for product authorisation – details below the table
6	All **initial application for approval in progress**	N/A	One or more **new active substances**	The surface disinfectant **cannot** be made available

				(supplied) and used in the UK
7	Some **approved**, **some initial application for approval in progress**	N/A	One or more **new active substances**	The surface disinfectant **cannot** be made available (supplied) and used in the UK
8	One or more **not approved**	N/A	N/A	The surface disinfectant **cannot** be made available (supplied) and used in the UK
9	One or more **expired**	N/A	N/A	The surface disinfectant **cannot** be made available (supplied) and used in the UK
10	One or more are not listed in the database			The surface disinfectant **cannot** be made available (supplied) and used in the UK
11	One or more **cancelled application**			Email biocidesenquiries@hse.gov.uk for advice

12	One or more **no longer supported**	Email biocidesenquiries@hse.gov.uk for advice

Product authorisation needed

If the combination of active substances in your surface disinfectant products fits into scenario 1 or 2 in the table, you will need to apply for product authorisation under the Biocidal Products Regulation (BPR) to supply the products in the UK. Our product authorisation pages (www.hse.gov.uk/biocides/eu-bpr/national-authorisation.htm) provide more details.

You must also ensure that you comply with all of the requirements under the heading ‘General legal requirements for surface disinfectant products’.

No product authorisation needed

If the combination of active substances in your surface disinfectant products fits into scenarios 3-5 in the table, you **do not** need a product authorisation or any specific derogation from HSE to supply the products in the UK – that would only be required once the review of the all of the active substances has been completed and they gain approval under BPR, or the approval dates are reached.

You must ensure that you comply with all of the requirements under the heading ‘General legal requirements for surface disinfectant products’.

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:
www.hse.gov.uk/news/assets/docs/surface-disinfectant-manufacture-supply-coronavirus.pdf

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