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

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

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 are manufacturing or importing hand sanitising products you must comply with whichever regulations are relevant for each product in your range.

Hand sanitising products fall into one of three regulatory groups depending on the products' intended use, function, composition or how they are described:

- Products primarily used to clean and/or moisturise skin while providing a secondary antimicrobial effect, such as a liquid soap or solid soap bars, are classed as a **cosmetic**. The regulations that apply 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 make claims to treat/prevent infections associated with specifically named pathogens (such as COVID-19) are classed as **medicines**, as are products specifically used as surgical scrubs for use in operating theatres.

  Marketing Authorisations (www.gov.uk/topic/medicines-medical-devices-blood/marketing-authorisations-variations-licensing) are required for medicines. Contact the Medicines and Healthcare products Regulatory Agency (MHRA) at borderline_medicine@mhra.gov.uk for information and advice.

- Products primarily claiming to kill germs, disinfect or sanitise using an active antimicrobial ingredient, such as hand sanitisers, are classed as a **biocide**. Please note that general hand sanitiser products are not permitted to 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 are supplying biocidal hand sanitiser 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 biocidal hand sanitiser 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 biocidal hand sanitiser products you supply in the UK.

REACH

If you import biocidal hand sanitiser 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 hand sanitiser 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 hand sanitiser 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 (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)

During this exceptional time of increased demand due to the coronavirus outbreak, it may be necessary for hand sanitiser manufacturers 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 in the UK to help protect people during the coronavirus outbreak. HSE will adopt a pragmatic and proportionate approach to regulatory requirements that relate to supply chain obligations during this period. The focus of any HSE activity by inspectors will be to ensure that products on the market are effective in combating the coronavirus and do not pose an unacceptable risk to people or the environment.

HSE would expect product manufacturers to have taken all reasonable steps to source ingredients in such a way that they are 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, recognising the urgent wider need for safe and effective products.

If you are going to use a source that is not Article 95 listed, keep a record of the actions you have taken to try to source the active from Article 95 listed companies in case you are asked to justify that decision at some point in the future. For example, if there has been email communication with Article 95 listed suppliers and you have been unsuccessful in obtaining a source of the active substance, then such emails could demonstrate reasonable steps to try to source ingredients that would be Article 95 compliant. Alternatively, if such enquiries are made over phone, ensure you keep a record of the call and follow up with email confirmation.

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.

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

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 (www.hse.gov.uk/biocides/eu-bpr/informing-npis.htm).

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

Additional requirements may apply to your hand sanitiser products depending on the active substance they contain. See the relevant section(s) in this document for more information.

Ethanol-based products

Ethanol (CAS 64-17-5; EC 200-578-6) has been supported for assessment under the BPR review programme for use in Product type 1 – human hygiene biocidal products (which would include hand sanitisers) and is still undergoing that assessment. This means you **do not** need a product authorisation or any specific derogation from HSE to bring an ethanol-based hand sanitiser to the UK market – that would only be required once the review of ethanol has been completed and it gains approval under BPR.

Although there are no specific BPR requirements for the grade of ethanol that can be used in such biocidal products, WHO guidance on making hand sanitisers recommends that pharmacopoeia grade chemicals are used. The European Pharmacopoeia specification for ethanol allows for maximum amounts of common, potentially hazardous impurities. For example, methanol is identified as a potentially hazardous impurity that should not exceed 200 ppm (0.02%). The WHO guidance however, is a guide, not a legal requirement.

HM Revenue & Customs (HMRC) have provided industry with advice on changes to their rules for the supply of ethanol (www.gov.uk/guidance/producing-hand-sanitiser-and-gel-for-coronavirus-covid-19) – HSE cannot provide additional advice on HMRC's position.

You must also ensure that you comply with all of the requirements under the heading 'General legal requirements for biocidal hand sanitiser products'.

Propan-2-ol-based products

Propan-2-ol (CAS 67-63-0; EC 200-661-7) has already been approved as an active substance under BPR for use in Product type 1 – human hygiene biocidal products (which would include hand sanitisers). This means that hand sanitiser products based on propan-2-ol would normally require UK BPR product authorisation before they can be made available (supplied) and used in the UK. However, Article 55(1) of BPR) enables HSE to provide short-term derogations from the requirements for BPR authorisation in cases of danger to public health, animal health or the environment which cannot be contained by other means.

WHO propan-2-ol formulation

In response to the current shortages in supply of hand sanitisers, HSE has issued a Critical Situation Permit under Article 55(1) of BPR to enable hand sanitiser products, using the WHO-specified formulation based on propan-2-ol, to be quickly made available on the UK market. This derogation is only for the exact WHO-specified formulation, but it allows a broad number of companies or institutions to be permitted to supply and use the formulation, provided they comply with specific conditions.

While this action will enable manufacturers to supply hand sanitiser products in the UK quickly, HSE expects manufacturers to adhere to standards that protect people and the environment from hazardous chemicals.

Companies and institutions wishing to make use of the **existing derogation for the WHO formulation** should email biocidesenquiries@hse.gov.uk with 'Propan-2-ol Article 55 notification form' in the subject line.

There may be some delays due to the volume of notifications we expect to receive. **You must wait for our confirmation before suppling or using the products in the UK.**

You must also ensure that you comply with all of the requirements under the heading 'General legal requirements for biocidal hand sanitiser products'.

Other propan-2-ol formulations

If the hand sanitiser products you wish to make available (supply) use a propan-2-ol formulation that is **different in any way** from the WHO formulation, you will need to apply for a separate permit.

As part of your application you will be required to submit a data package relating to the safety and efficacy of your product.

We will process any such requests urgently. However, a technical assessment of the data package is required to ensure that the product meets the established standards that protect people and the environment, and that the product is effective. So this route may take significantly longer than requests made under the existing permit for the WHO formulation and will incur a charge.

Companies and institutions wishing to apply for a separate derogation for **propan-2-ol formulations that are different in any way from the WHO formulation** should email biocidesenquiries@hse.gov.uk with 'Hand sanitiser Article 55 application form' in the subject line.

There may be some delays due to the volume of applications we expect to receive. **You must wait for our confirmation before supplying or using the products in the UK.**

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

Products based on active chlorine generated from sodium chloride by electrolysis or active chlorine released from hypochlorous acid

If the hand sanitiser products you wish to make available (supply) uses a formulation that is based on:

- active chlorine generated from sodium chloride by electrolysis;
- active chlorine released from hypochlorous acid

you will need to apply for a separate permit.

This is because these active substances are not being assessed as part of the BPR active substance review programme. This means that biocidal products containing these active substances are not included in the transitional arrangements set out in Article 89 of BPR.

As part of your application you will be required to submit a data package relating to the safety and efficacy of your product.

We will process any such requests urgently. However, a technical assessment of the data package is required to ensure that the product meets the established standards that protect people and the environment, and that the product is effective.

Each application will incur a charge, which is determined by the volume of data assessment required.

To request an application form please email HSE’s biocides helpdesk biocidesenquiries@hse.gov.uk with ‘**Hand sanitiser Article 55 application form**’ in the subject line.

There may be some delays due to the volume of applications we expect to receive. **You must wait for our confirmation before supplying or using the products in the UK.**

You must also ensure that you comply with all the requirements under the heading ‘General legal requirements for biocidal hand sanitiser products’.

Other active substances

The UK regulatory requirements for hand sanitisers based on active substances other than ethanol and propan-2-ol vary depending on the approval status of the active substance(s) under BPR for use in Product type 1 – human hygiene biocidal products (which would include hand sanitisers).

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 product type 1 to see all of the relevant active substances for hand sanitisers, 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 hand sanitiser, check the table below for what you need to do.

Scenario	Approval/Assessment status	Approval start date	Regulatory Process	What you need to do
1	All **approved**	All in the past	N/A	Apply to HSE –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 to HSE –details below the table
3	All **initial application for approval in progress**	N/A	One or more **new active substances**	The hand sanitiser **cannot** be made available (supplied) and used in the UK

4	Some **approved**, **some initial application for approval in progress**	N/A	One or more **new active substances**	The hand sanitiser **cannot** be made available (supplied) and used in the UK
5	One or more **not approved**	N/A	N/A	The hand sanitiser **cannot** be made available (supplied) and used in the UK
6	One or more **expired**	N/A	N/A	Apply to HSE –details below the table
7	One or more are not listed in the database			The hand sanitiser **cannot** be made available (supplied) and used in the UK
8	All **approved**	Some in the future	Those with approval dates in the future are **review programme substances**	No need to apply to HSE –details below the table
9	All **initial application for approval in progress**	N/A	All **review programme substances**	No need to apply to HSE –details below the table
10	Some **approved**, some **initial application for approval in progress**	N/A	All **review programme substances**	No need to apply to HSE –details below the table

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

Application to HSE needed

If the combination of active substances in your hand sanitiser products fits into scenarios 1, 2 or 6 in the table, you will need to apply to HSE for a permit under Article 55(1) of BPR to supply the products in the UK during the coronavirus outbreak.

You will be required to submit a data package relating to the safety and efficacy of your product as part of your application.

We will process any such requests urgently. However, a technical assessment of the data package is required to ensure that the product meets the established standards that protect people and the environment, and that the product is effective. So this route will take significantly longer than requests made under the existing permit for the WHO formulation and will incur a charge.

Companies and institutions wishing to apply for a derogation should email biocidesenquiries@hse.gov.uk with 'Hand sanitiser Article 55 application form' in the subject line.

There may be some delays due to the volume of applications we expect to receive. **You must wait for our confirmation before supplying the products in the UK.**

You must also ensure that you comply with all of the requirements under the heading 'General legal requirements for biocidal hand sanitiser products'.

No application to HSE needed

If the combination of active substances in your hand sanitiser products fits into scenarios 8-10 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 the 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 biocidal hand sanitiser 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/hand-sanitiser-manufacture-supply-coronavirus.pdf

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