Supply of biocidal hand sanitiser products – guidance for Trading Standards

Hand sanitisers are alcohol-based or alcohol-free liquids, gels or foams that are designed to decrease pathogens such as bacteria or viruses on the hands. As a result of the COVID-19 pandemic there has been unprecedented demand for hand sanitiser products and, to meet this demand, there has been rapid growth in the number of businesses and individuals producing and supplying hand sanitiser products.

Hand sanitisers may fall within scope of biocides legislation depending on the products' intended use, function, composition or how they are advertised. If so, there are strict rules governing their supply which are relevant to producers, importers, distributors, retailers and other suppliers of these products.

This guidance is for Trading Standards Officers and offers advice on the application and enforcement of biocides legislation (and other relevant chemicals regulations) to hand sanitisers.

What are biocidal products?

Biocidal products are defined in Regulation (EU) No. 528/2012 concerning the making available on the market and use of biocidal products, usually referred to as the Biocidal Products Regulation or BPR. Article 3 of the BPR states that a 'biocidal product' is one which meets the following four criteria:

- any substance or mixture;
- in the form in which it is supplied to the user;
- consisting of, containing or generating one or more active substances;
- with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

In addition, the product should fall within one of the 22 product types described in Annex V of the BPR.

Hand sanitisers fall under Product Type 1 (PT1) for human hygiene disinfectants. Such disinfectants are described as "*Biocidal products used for human hygiene purposes, applied on or in contact with human skin or scalps for the primary purpose of disinfecting the skin or scalp*."

How can I tell if a hand sanitiser is a biocidal product?

While hand sanitisers are often within scope of biocides legislation, they can fall within scope of other legislative regimes instead. Hand sanitising products tend to fall into one of three regulatory groups depending on a product's intended use, function, composition or how they are described/advertised:

- Products used to clean and/or moisturise hands (even if they claim to provide a secondary antimicrobial effect) such as a liquid soap or solid soap bars are likely to be classed as a **cosmetic product**.

- Products claiming to kill germs, disinfect or sanitise or prevent cross-contamination are likely to be classed as a **biocidal product**.

- Products presented as principally preventing or treating a disease or adverse condition are likely to be classed as a **medicinal product**.

Biocides legislation does not normally apply to products that are within scope of cosmetic products or medicinal products legislation. This means BPR usually only applies if other legislation does not.

If you believe the product could be classed as a medicine you are encouraged to seek a view from MHRA on the scope of the product before concluding it is a biocidal product – you can contact MHRA in such instances at borderline_medicine@mhra.gov.uk

As Trading Standards enforce cosmetic products legislation, you should also consider whether you believe the product could be classed as a cosmetic before proceeding under biocides legislation.

Authorisation of biocidal products

Under Article 17(1) of BPR, biocidal products must not be made available on the market or used if they have not been authorised in accordance with this Regulation. BPR sets up a two-stage process for product authorisation:

- First, the biocidal active substance (e.g. propan-2-ol, CAS no. 67-63-0, EC no. 200-661-7) which is being used in a product to have a particular controlling effect on the target organism (e.g. kills viruses / bacteria) needs **'approval'** for the particular product type (e.g. PT1 – human hygiene disinfection). This evaluation process takes place at the EU level for every combination of active substance and product type (PT) that businesses have chosen to support. Its outcome sees an active substance 'approved' or 'not approved' for use in one or more product types.

- Second, the product that contains the active substance needs **'authorisation'** for the way that specific product is going to be used (e.g. to kill viruses on the hands of people using the quantity X at Y hourly intervals in Z circumstances). Biocidal products must be authorised in each Member State in which they are to be made available on the market. In the UK, HSE is the body that receives and evaluates applications for product authorisation and decides whether authorisation should be granted.

However, authorisation is not yet required for every biocidal product because we are in a **transition period**. The outcome of the review process will either see an active substance 'approved' for use in one or more product types, or its use will not be approved, meaning that all relevant products containing it will be withdrawn from the market.

Under transitional arrangements laid down in the BPR, biocidal products containing active substances that are still under review for a particular product type do not yet need authorisation for that product type and can continue to be placed on the market in line with the transitional arrangements of the BPR. (There is an exception to this for 'new' active substances not listed in the review programme, in which case these transitional arrangements do not apply.)

Where a product contains more than one active substance, product authorisation is not required until all of the active substances in it have been approved. In other words, authorisation is only required once the last of the active substances in the biocidal product has been approved.

However, if an active substance is neither approved nor under review for use in a particular product type, then it is not being supported under the BPR and any biocidal product of that product type that contains it cannot lawfully be placed on the market.

The table in the section below summarises the circumstances in which a biocidal product can and cannot be made available on the market with or without a product authorisation.

How can I find out if a biocidal product needs authorisation yet?

To do this, you need to find out the approval status of the active substance(s) in the product.

If you don't know what the active substance in any given hand sanitiser is, then you can find out by requesting this information from the supplier, examining the label and/or looking at section 3 of a safety data sheet (SDS). You should always try and obtain the substance's CAS or EC number, not just its name, because these numbers will help you identify the substance with more certainty.

The European Chemicals Agency (ECHA) website (https://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances) provides details on the approval status of all biocidal active substances under the Biocidal Products Regulation (BPR) and can be filtered by product type, e.g. PT1 for hand sanitisers.

Once you know the status of all the active substance(s) in a hand sanitiser, the regulatory requirements that apply are set out below:

Active Substance(s) Status	UK Regulatory Requirements
All the active substances in the product are "**approved**" for PT1 and the dates of approval for all the active substances have now passed. *e.g. propan-2-ol, propan-1-ol, hydrogen peroxide, active chlorine released from sodium hypochlorite etc.*	The hand sanitiser (PT1 biocidal product) requires BPR product authorisation before it can be made available (supplied) and used in the UK (*unless an application for product authorisation was submitted before the approval date, or a derogation has been granted – see below*). Details of the product authorisation process can be found on HSE's website at www.hse.gov.uk/biocides/eu-bpr/national-authorisation.htm.
All the active substances in the product are, for PT1, either: a. "**under review**", or b. some of the active substances are "**under review**" and some are "**approved**", or	The hand sanitiser (PT 1 biocidal product) can be made available (supplied) and used in the UK without yet needing BPR product authorisation. However, suppliers must still comply with the following: • Advertising rules under Article 72 BPR

c. all of the active substances are "**approved**" but it is before the last approval date *e.g. ethanol, DDAC, ADBAC/BKC (C12-16) etc*	• Rules on sourcing the active substance(s) from a BPR approved Article 95 listed business • Record keeping rules under Article 65 and 68 of BPR (see HSE's website at https://www.hse.gov.uk/biocides/eu-bpr/recording-keeping-reporting.htm for more) • Other applicable chemicals regulations such as that on classification, labelling and packaging (CLP) and REACH (see below for more) Any workplace where hand sanitisers are produced, used or stored must also comply with relevant health and safety regulations, e.g. COSHH and DSEAR.
One or more of the active substances in the product is listed for PT1 as "**expired**", "**not approved**" or is **not listed**	The hand sanitiser (PT1 biocidal product) cannot be made available (supplied) and used in the UK.
One or more of the active substances is listed for PT1 as "**cancelled**"	Contact HSE for further advice.

How can I find out if a biocidal product is authorised?

If the product has been authorised then the label should show the authorisation number, which will typically appear on the label in a form such as UK-(number) or EU-(number), along with other relevant biocidal use-related information.

You may also be able to find the product by searching HSE's biocidal product database (although bear in mind that if you don't find a given product on this database it doesn't necessarily mean it is being placed on the market illegally, e.g. it might not yet require authorisation or may be covered by a different type of product authorisation under BPR).

Derogations from authorisation

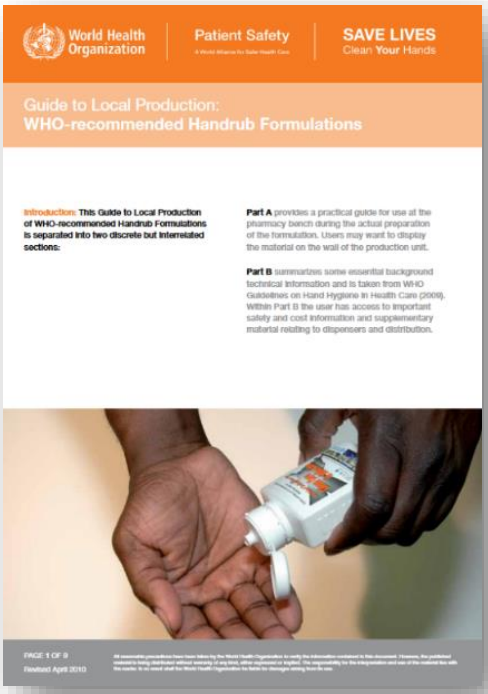
Article 55(1) of BPR enables HSE, in cases of danger to public health, animal health or the environment which cannot be contained by other means, to provide short term derogations from the requirements for product authorisation.

To meet the increased demand for hand sanitisers, HSE is working closely with other Government agencies, manufacturers and their trade associations. As part of this, HSE has made arrangements to issue derogations from product authorisation requirements for hand sanitiser products.

To date, these apply mainly to hand sanitisers containing **propan-2-ol** (also called isopropanol, isopropyl alcohol or IPA). Propan-2-ol has already been approved as an active substance for PT1 meaning that hand sanitisers containing it should be authorised before being placed on the market. However, suppliers who do not currently have an authorisation can apply for a derogation from product authorisation under Article 55 of the BPR. These applications will be 'fast-tracked' if a product's formulation meets the relevant World Health Organisation (WHO) specification; if not, a derogation can still be granted but it will require more scrutiny.

Any supplier wishing to take advantage of these arrangements must first contact HSE via biocidesenquiries@hse.gov.uk using 'Propan-2-ol Article 55' as the subject title of the email. Products should not be placed on the market until HSE has confirmed that the derogation applies to them.

Similarly, **propan-1-ol** has been approved for PT1 use and suppliers of hand sanitisers that contain it as the (only) active substance can also apply for Article 55 derogation. However, there is no agreed WHO specification for products with propan-1-ol as the active substance and so applications may take longer to assess.



Many hand sanitisers contain **ethanol** (ethyl alcohol) as their active substance. Ethanol-based hand sanitisers are not subject to these arrangements because ethanol is still under review for PT1 products, meaning that product authorisation is not yet required (and consequently no derogation from authorisation is required). However, the WHO guidance referred to above also contains a specification for ethanol-based hand sanitisers that suppliers can use in order to demonstrate their product is effective (see more on this below).

For more information, see HSE's website.

How can I verify the supplier's claims about their product's effectiveness?

If a biocidal product has already been authorised by HSE then this means that the authorisation holder has provided information which has demonstrated to HSE's satisfaction that the product is effective for the uses that have been authorised.

However, effectiveness (efficacy) is only formally assessed at the product authorisation stage. Not all biocidal products require authorisation yet and, for products not yet authorised, there's no clear-cut way to determine whether they are effective. It's worth bearing in mind that if a product is not authorised this doesn't mean it's not effective.

- For alcohol-based hand sanitisers, if they have been produced to the WHO specification then they are likely to be effective against the COVID-19 virus.

- For non-alcohol-based hand sanitisers the position is less clear and claims about effectiveness will need to be assessed on a case-by-case basis. A good first step to take would be to approach the supplier making the claims and ask them to demonstrate how they know their product is effective in that respect. After all, if a supplier is making efficacy claims (e.g. "kills 99.99% of bacteria" or "effective against viruses" etc) then they should have robust scientific evidence to back them up.

If product suppliers provide EN standard tests to support the efficacy of their products the document 'Volume II Efficacy – parts B+C: Assessment and Evaluation' (available at https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation), in particular appendices

2 and 4, may help you quickly establish if the tests you have been provided are appropriate for the uses claimed. This document provides a summary of the EN standards typically used to assess disinfectant efficacy and the types of test conditions and results required to establish basic efficacy against different types of organism. This document should, however, only be used as an indicative guide. The criteria given are not fully applicable until products are being considered for product authorisation under the BPR.

MHRA has advised HSE that antibacterial hand gels and hand sanitisers are not normally considered to be medical devices or medicinal products unless they are specifically surgical scrubs for use in operating theatres or make claims to treat/prevent infection associated with specifically named pathogens. This means that general hand sanitiser products should not name specific pathogens. Claims to treat or prevent infection associated with specifically named pathogens (such as Covid-19) could bring the product within the remit of medicinal products legislation. Please refer to Appendix 5 in MHRA's Guidance note 8 – 'A guide to what is a medicinal product' for further information.

If you require further information and advice with respect to the naming of specific pathogens please contact the MHRA Medicines Borderline Section at borderline_medicine@mhra.gov.uk

On occasion suppliers have been found to be supplying product that has a different composition to that advertised, e.g. with different ingredients in the formulation. In some cases, analysis undertaken on alcohol-based products has revealed far less active substance (e.g. ethanol) present to that advertised. This is likely to affect the efficacy of a product. Where there is cause to suspect this, you should consider obtaining a sample of product for testing.

Advertising and labelling requirements

Article 69 of the BPR lays down requirements for labelling, although these requirements apply only once a product has been authorised. More information on BPR labelling requirements can be found at https://www.hse.gov.uk/biocides/eu-bpr/packaging-labelling-requirements.htm. However, more general labelling requirements under the CLP Regulation might still apply – see below for more on CLP labelling.

Article 72 of the BPR lays down requirements for advertisement which apply to all biocidal products, not just those requiring authorisation. It says that, in addition to complying with any applicable CLP requirements for advertising, adverts for biocidal products must include the sentences "*Use biocides safely. Always read the label and product information before use*." These sentences must be clearly distinguishable and legible in relation to the whole advertisement.

In addition, Article 72 also states:

> "*Advertisements for biocidal products shall not refer to the product in a manner which is misleading in respect of the risks from the product to human health, animal health or the environment or its efficacy. In any case, the advertising of a biocidal product shall not mention 'low-risk biocidal product', 'non-toxic', 'harmless', 'natural', 'environmentally friendly', 'animal friendly' or any similar indication*."

Article 72 of the BPR is enforced by Trading Standards – see below for more information on enforcement responsibilities.

Sourcing active substances

Article 95 of the BPR aims to ensure that the costs of generating data and supporting active substances through the review programme are shared fairly. Under Article 95, all businesses making biocidal products available on the UK market have to be able to demonstrate that their active substance supplier is included in a list, known as the Article 95 list. The Article 95 list is maintained by ECHA and can be found on their website.

However, during this exceptional time of increased demand due to the COVID-19 outbreak, it may be necessary for hand sanitiser manufacturers to find alternative suppliers of raw ingredients to supplement those obtained via regular supply chains. Because of this, HSE has temporarily altered its approach to the enforcement of Article 95. For more information, please see www.hse.gov.uk/news/hand-sanitiser-manufacture-supply-coronavirus.htm.

Classification, labelling and packaging of biocidal hand sanitisers

Suppliers of biocidal hand sanitisers are also likely to have duties under Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP).

CLP requires suppliers of chemical substances or mixtures to identify their hazards (dangers) before placing them on the market. This process is known as '**classification**' and involves suppliers assessing whether a chemical can cause harm by comparing its properties against criteria in the CLP Regulation, for example, to determine whether it is toxic, or is flammable, or has the potential to cause cancer or skin sensitisation etc.

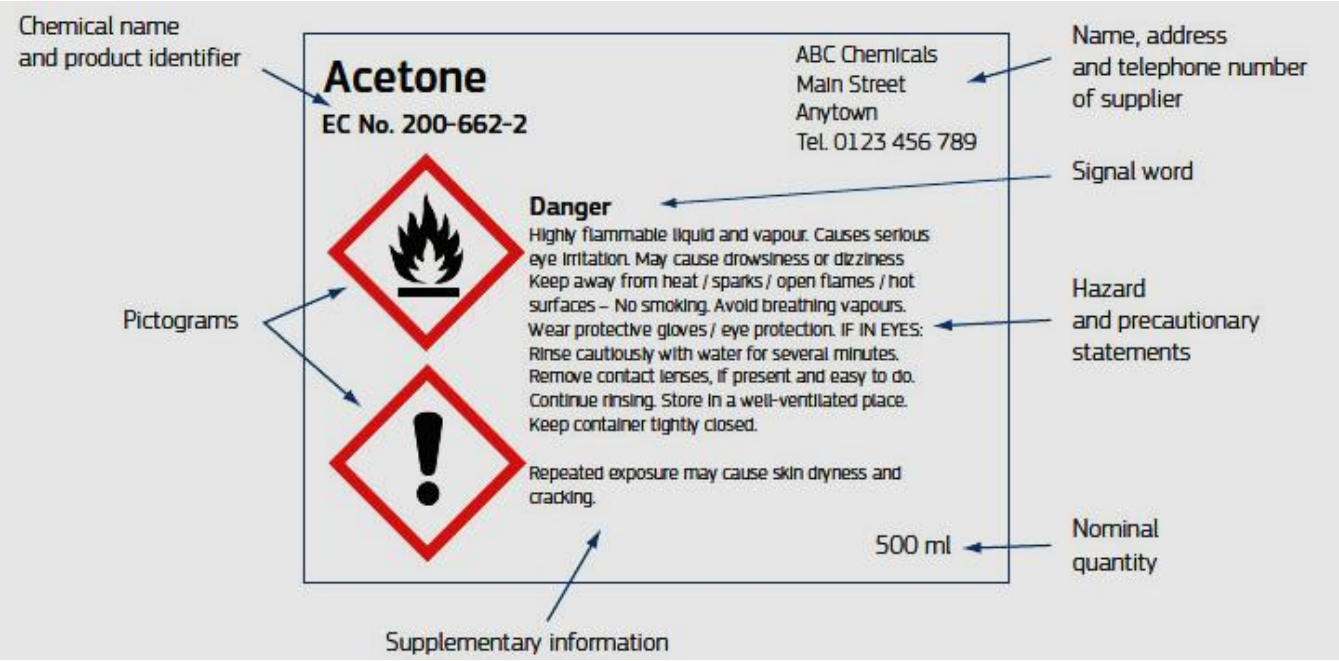
Chemicals are classified so that people using them – either in industry or as consumers – can understand any hazardous effects they could have on human health or the environment and to protect against that harm.

If a substance or mixture meets the criteria for classification as hazardous, then this triggers further requirements in CLP to ensure they are labelled and packaged in line with the Regulation:

- **Labelling** requirements (Articles 17 to 33 of CLP) allow the hazards to be communicated to the user of a substance or mixture, to alert them about the presence of a hazard and the need to manage the associated risks. CLP requires certain information to be present on the label of any hazardous product (with certain exemptions, e.g. for very small packaging). Additionally, suppliers will need to supplement their label after biocidal product authorisation to meet the requirements of Article 69 of the BPR.

  An example of a CLP label is provided below that shows the standard labelling elements stated in Article 17(1) of CLP (NB. this does not relate to a biocidal product).

- **Packaging** requirements (Article 35 of CLP) are aimed at ensuring the chemical can't escape its container, e.g. that the packaging is strong, solid and resistant to damage by its contents or during normal or foreseeable use. Packaging requirements also provide for the application of tactile warnings of danger and child-resistant fastenings for products supplied to consumers that have certain hazards, as well as requirements that the product must not attract / arouse the curiosity of children or resemble food, drink, animal feed, medicinal products or cosmetic products.



Many hand sanitiser products will meet the criteria for classification as hazardous under CLP. For instance, alcohol-based hand sanitisers with at least 60% alcohol content are likely to be classified as category 2 flammable liquids and might also have other hazards such as eye irritation or specific target organ toxicity. If a product is classified as hazardous but bears no CLP labelling at all, this is of concern because the supplier will not be properly communicating the product's hazards to its users, who are therefore much less likely to take appropriate precautions against the associated risks.

However, CLP requirements, in particular, its rules on chemical classification, are not straightforward and you are advised to seek advice from HSE before taking enforcement action.

You can find much more information about CLP on ECHA's website.

Enforcement of biocides and CLP

Enforcement of the BPR is the responsibility of both HSE and Trading Standards under the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 (BPCR).

In general, enforcement responsibilities are split based on who the product is being supplied to, with Trading Standards leading on breaches where products have been supplied to consumers, and HSE leading on breaches where products are sold business to business. Typically this involves Trading Standards being responsible for enforcement of BPR at retailers (including online retailers and trading platforms such as Amazon and eBay) and HSE being responsible for supply that occurs further up the supply chain, including by formulators of biocidal products. However, this is not always the case, for example, some formulators may sell direct to the public.

There are some provisions in BPR that are exclusively enforced by Trading Standards, such as its provisions on advertising (Article 72).

Enforcement of CLP is also set out in BPCR and follows a similar divide to that described above. Again, some provisions are enforced exclusively by Trading Standards, such as provisions on packaging in Article 35(2) and advertising in Article 48.

Other regulatory requirements

Exports: If a supplier is exporting biocidal products from the UK to another EU country then they must meet the requirements of the BPR (as it is EU legislation) and any other national legislation in that EU country.

If a supplier is exporting directly from the UK to a non-EU country then the requirements of the BPR do not apply, but there may be other UK legislation they need to comply with such as that on Prior Informed Consent (PIC) or specific customs and export rules. They should also check if there is any legislation they need to comply with in the importing country.

Imports: If a business is importing chemicals, they may have obligations under REACH to register substances they are importing at 1 or more tonnes per year (with the exception that biocidal active substances do not require separate registration under REACH).

Suppling chemicals: Suppliers of chemicals that are classified as hazardous under CLP need to ensure they provide recipients (except for consumers) with a safety data sheet (SDS) that has been compiled to REACH requirements. There are some circumstances when a SDS does not need to be provided, e.g. where hazardous substances or mixtures offered or sold to the general public are provided with sufficient information to enable users to take necessary measures for the protection of human health, safety and the environment, unless one is requested by a downstream user or distributor.

Handling / storing chemicals: Those producing biocidal products, as well as those handling, using or storing them, must also comply with applicable requirements of occupational health and safety legislation under the Health and Safety at Work etc Act 1974 and related statutory provisions such as DSEAR and COSHH.

Further information & contacts

Further information on biocides can be found both on HSE's website and on ECHA's website.

The Enforcement Team in HSE's Chemicals Regulation Division (CRD) leads on the enforcement of biocides, CLP and other chemicals regulation within HSE and can provide further help and advice to Trading Standards. The team is based predominantly at our Bootle and York offices and can be contacted via CRDEnforcement@hse.gov.uk.

Dutyholders wanting general advice and help on understanding biocides legislation can contact HSE's Biocides Helpdesk via biocidesenquiries@hse.gov.uk. Similarly, dutyholders wanting more advice and guidance on CLP can contact the CLP Helpdesk via UKREACHCA@hse.gov.uk.

In offering this guidance, HSE wishes to make it clear that:

- Only the courts can interpret legislation with any authority.
- This advice is not intended to be a definitive guide to, nor substitute for, the relevant law.
- Independent legal advice should be sought where appropriate.

June 2020 (rev)