

Hand Sanitisers and Gels Legal Requirements – General Information & FAQ's

Placing products on the Market - what do I need to know?

Based on current guidance, hand sanitising products fall into one of three regulatory groups:

1. **Cosmetic:** Products used to clean and/or moisturise hands whilst providing a secondary antimicrobial effect such as a liquid soap or solid soap bars, are classed as a **cosmetic**.
2. **Biocide:** Products claiming to kill germs, disinfect or sanitise or prevent cross contamination such as the hand sanitisers used in hospitals, are classed as a **biocide**.
3. **Medicine:** Products presented as principally preventing or treating a disease or adverse condition, are classed as a **medicine**

This applies to hand gels, hands rubs and hand sanitisers, whether manufactured in the UK or imported from another country.

Each product will need to be assessed on a case by case basis.

Below are some links to guidance on the various product compliance routes to get you started. We would strongly advise that whichever part you play within the supply chain (importer, manufacturer or distributor) that you contact your local Trading Standards department (<https://www.gov.uk/find-local-trading-standards-office>) for advice to ensure your product is safe and legally compliant.

- **Cosmetic products:**

Must comply with the EU Cosmetic Products Regulation.

Clear guidance for supplying cosmetic products is available on the UK Cosmetics Trade Association (CTPA) website <https://www.ctpa.org.uk/supplying-or-manufacturing-a-cosmetic-product>

Specific hand sanitiser guidance:- <https://www.ctpa.org.uk/news/placing-hand-gels-or-sanitisers-on-the-uk-market-what-you-need-to-know-4448>

- **Biocidal products:**

Must comply with the EU Biocidal Products Regulation.

These Regulations are mostly under the remit of the Health and Safety Executive (HSE) and can be contacted via this email:- biocidesenquiries@hse.gov.uk

Aspects relating to the marketing and sale of a biocidal product falls to the remit of Trading Standards.

Comprehensive advice is available on the HSE website:-<https://www.hse.gov.uk/biocides/index.htm>

UPDATE: 30/03/20: The rules have been relaxed slightly to assist in getting hand sanitiser products to the market quicker. Please read this updated guidance from the HSE <https://www.hse.gov.uk/news/hand-sanitiser-manufacture-supply-coronavirus.htm>

- **Medicinal products:**

Must comply with the Human Medicines Regulation.

This legal framework falls under the remit of the Medicines and Healthcare products Regulatory Agency (MHRA).

Please follow the link below to determine whether your product is a medicine

<https://www.gov.uk/guidance/decide-if-your-product-is-a-medicine-or-a-medical-device>

For further advice you can contact the MHRA via email to this address:-

borderline_medicine@mhra.gov.uk

NB: It is illegal to place any of these product types on the UK market without complying with the relevant regulation

FAQ's

1. I am thinking of diversifying my business and looking to manufacture hand sanitiser, what do I need to do?

Firstly, you will need to determine which legal framework route your product will fall under. For help with this please have a read through the advice links above and then contact your local Trading Standards department.

Also read the new HMRC Covid-19 support information: **Temporary changes to the use and supply of denatured alcohol and duty-free spirits, to help businesses who produce hand sanitiser and gel:**

<https://www.gov.uk/guidance/producing-hand-sanitiser-and-gel-for-coronavirus-covid-19> and the **guidance on HMRC licensing around production/sale of denatured alcohol:**

<https://www.gov.uk/guidance/denatured-alcohol-producing-stocking-distributing-selling-and-using>

2. Importing hand sanitiser – what do I need to do?

Importing hand sanitiser from outside the EU has some very strict controls and legal requirements before they can be placed on the UK market and sold to consumers. Controls include types of ingredients, composition, formulations, labelling and authorisations.

Hand sanitisers and gels will fall under one of three different areas of legislative requirements as outlined above.

Advice links on all three areas including the details for the appropriate enforcing Agency can be found here and we suggest that you read these carefully and then contact the relevant agency for further advice:- <https://www.ctpa.org.uk/news/placing-hand-gels-or-sanitisers-on-the-uk-market-what-you-need-to-know-4448>

3. I am buying hand sanitiser/gel in bulk and want to repackage into smaller containers to sell to the public, are there any rules on what I need to do for this business activity?

You will need to ensure the product is safe, meets the relevant legal requirements, and label each individual smaller container correctly. This label will need information such as your business name and address, instructions for use, hazard warnings, batch number and ingredients/composition for starters. Please contact your local trading standards department for further advice on this activity.

4. There are many formulations on the web for manufacturing hand sanitiser/gels – can you recommend one?

We are unable to advise on a specific formulation however there is a local production hand rub formulation guide that has been produced by the World Health Organisation (WHO):-

https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf

5. Can I claim that the hand sanitiser/gel kills the Corona Virus? What other claims can I make?

No. Any such claims, as well as needing substantiation, are highly likely to mean the product is a medicine and would need testing to medicinal standards.

6. Can I mix isopropyl alcohol and Aloe Vera gel to make a hand sanitiser and place it on the market?

No. This formulation alone will not meet the strict legal requirements for such products, whichever route of compliance you follow. For example, you will not know whether the concentration is correct and effective or is too harsh.

7. If I manufacturer to the World Health Organisation published formulas, am I exempt from all legislative requirements?

No. However, the HSE Covid-19 guidance has relaxed some rules. Please contact Hertfordshire Trading Standards to discuss further.

8. Are there any rules on what I can charge for hand sanitiser/gels?

Grossly inflated prices could be deemed as an aggressive practice under the Consumer Protection from Unfair Trading Regulations. We would expect businesses to trade using the general principle of good faith in all fields of activity.

9. Where do I go to if I need further advice or support?

Hertfordshire Businesses can obtain further advice by contacting the Hertfordshire Trading Standards Business Advice Hotline – **01707 281401** or by email to tradingstandards@hertfordshire.gov.uk