in focus

Aligning hand hygiene products with regulatory frameworks in the age of COVID-19

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With the COVID-19 pandemic in its second year, the consumer hand hygiene product category is gaining much attention. But there are many factors that manufacturers need to consider. For instance, is it better to opt for cosmetic or biocidal product positioning? What are the key factors driving purchase, how important is scientific evidence of effectiveness, and do people trust the claims made on product labels? This report looks at a consumer study conducted by TSG Consulting. We consider how manufacturers can respond to heightened demand while navigating complex hand hygiene product regulations both within and between international markets.

Increased demand for hand hygiene products

When COVID-19 first hit the headlines in 2020, sales of hand hygiene products such as antibacterial soap and hand sanitizer soared. Around the world, retailers' shelves were stripped bare of these products as consumers stocked up. A global shortage prompted several distilleries and breweries to switch from producing alcoholic beverages to alcohol-based hand rubs[1]. In some countries, this was facilitated by regulatory adjustments to expedite production.

Consumer research

TSG Consulting commissioned consumer research in Canada, France, Germany, Spain, the United Kingdom (UK) and the United States of America (USA) to ascertain which hygiene products have been purchased in response to COVID-19. Our goal was to better understand what consumers want from these items as well as their thoughts on factors such as efficacy, claims, and labeling.

Fieldwork was undertaken between 21 December 2020 and 8 January 2021, with a total of 8,828 adults completing the online interview. Findings and statistics referenced in this report relate to the full sample, across all six countries, unless otherwise stated. The figures have been weighted and are representative of all country adults (aged 18+).

67% of consumers surveyed have bought an antibacterial hand wash or hand sanitizer in response to COVID-19.

What's the situation now?

Today, the supply issues affecting hand hygiene products have largely been resolved, but they remain in high demand. According to research we commissioned in Canada, France, Germany, Spain, the UK and USA, hand hygiene products were more likely to be purchased than any other hygiene goods in response to COVID-19. On average, 67% of adults in the six countries have purchased hand sanitizer or antibacterial hand wash due to the pandemic. The purchase rate exceeded 75% in the UK (77%) and Spain (83%); see a full breakdown in Figure 1. The next most popular product was antibacterial sprays and wipes, purchased by 47% of adults across all six countries. (A dedicated report looking at household products is available at www.tsgconsulting.com/household-biocides-report).

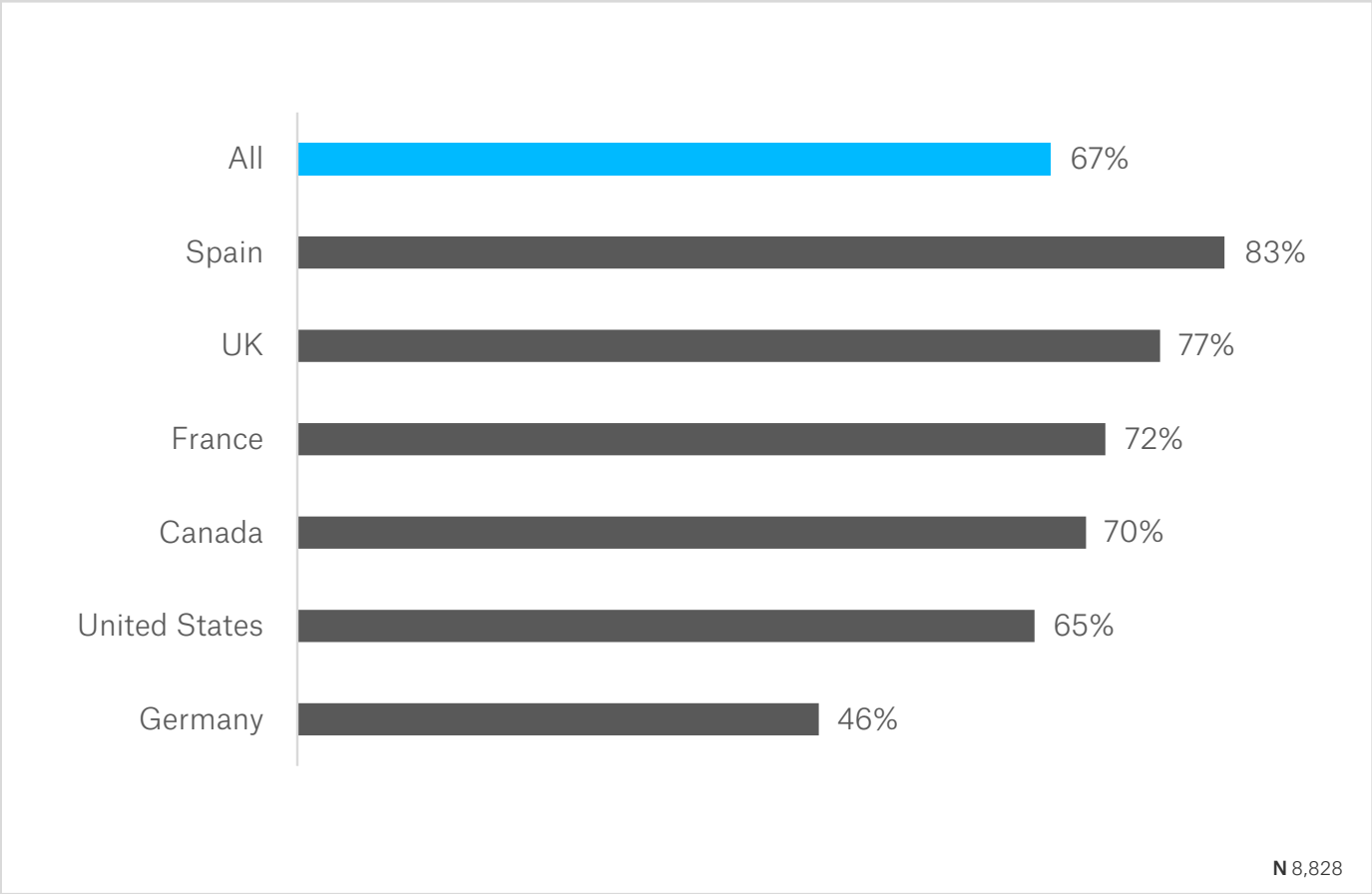


Figure 1: Percentage of consumers purchasing antibacterial hand wash or hand sanitizer for personal use because of coronavirus (COVID-19)

Is your hand hygiene product a cosmetic or a biocide?

Our research shows that, on average, 65% of people purchasing hygiene products in response to COVID-19 did so to protect themselves and their loved ones (Figure 2). As the pandemic continues to affect our lives, this remains a priority.

Nevertheless, there is a strong desire to resume more normal ways of living. Convenient, leave-on hand sanitizers that people can carry with them play an important role facilitating this.

Manufacturers wanting to launch new hand sanitizers or take existing ones to new markets need to be aware of the associated regulatory requirements. Understanding what consumers want, then aligning that with regulatory frameworks in different markets, is essential.

For instance, while global regulatory frameworks share the overarching goal of ensuring hand hygiene products are safe and effective, classifications and requirements can vary considerably. The situation is particularly complex in the European Union (EU) and Great Britain (GB). In these markets, a hand wash or hand rub may be categorized as a cosmetic, a biocidal product or even a medicinal product depending on its formulation, purpose, primary function, presentation, and claims.

Figure 2: Findings related to the question "Thinking about any of the products mentioned previously that you have purchased for personal use because of coronavirus (COVID-19) (e.g. sanitizers, disinfectants, devices such as UV disinfection boxes, ozone sanitizing machines, foggers, etc.) ...Which, if any, of the factors listed were important to you when deciding to purchase them? (Please select all that apply)"

The EU situation

While biocidal and cosmetic products have clear definitions, in some cases the borderline is not absolute, and products may well fit both categories. In these situations, it is important to clearly determine which legal framework to align with.

In the EU, if a hand hygiene product's antimicrobial effects are secondary to the primary function of cleaning the hands, the Cosmetic Products Regulation (CPR) can apply. However, if the product is positioned as an agent to kill germs or disinfect hands, it is classed as a biocidal product. In this case, compliance with the EU Biocidal Products Regulation (BPR) is required.

Biocidal product positioning can be led by antibacterial or disinfection claims, but the BPR requires registration in each country where the product is placed on the market. CPR requirements are more straightforward as one dossier can be used to cover the entire EU market.

The positioning may impact a product's appeal to different demographics too. When we asked consumers which product features or claims were important to them, 67% of 18-24 year olds said 'effectively kills germs/bacteria' whereas the figure within the 55+ age group was 84%.

Ideally, the decision about whether to align with cosmetic or biocidal regulations in the EU and GB markets needs to be made as early as possible in the product development process. Regulatory requirements can impact many aspects of a product, from formulation to labeling.

For a biocidal product, a fundamental requirement is that it contains a biocidal active substance at an effective concentration. Nevertheless, it is permissible for a cosmetic product to contain antibacterial ingredients and potentially make a biocidal claim, provided that the claim is secondary to the cosmetic function of the product and is supported by efficacy data. When it comes to leave-on cosmetics, biocidal claims should be used with caution: as a result of COVID-19, new guidance has been published defining claims that are not acceptable in cosmetic products (and would trigger the classification as a biocide). On the other hand, if a product contains ingredients which exceed concentration limits specified by the CPR, it cannot be sold as a cosmetic.

To add to the complexity, under transitional measures (which apply before the approval of an active substance) biocidal products need to be notified or authorized at the member state level. This is not harmonized, which means administrative and data requirements can vary. So, placing a biocidal hand hygiene product on the EU market when the active substance is still under evaluation presents additional challenges.

EU regulations impacting hand hygiene products

The EU Biocidal Products Regulation (528/2012) defines a biocidal product as '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'.

According to the EU Cosmetics Regulation (1223/2009), a cosmetic product is 'any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours'.

Changes in the UK

The UK's departure from the EU single market and customs union raises some uncertainty about how regulatory requirements might evolve. For the short to medium term, rules in Great Britain (i.e. England, Scotland, Wales and associated islands) will remain similar to those of the EU as the GB Biocidal Products Regulation (GB BPR) is a copy of the EU BPR; the same is true for the Cosmetic Products Regulation. However, there is likely to be a gradual divergence over time and TSG is keeping a close watch on the situation.

Biocidal products placed on the market in Northern Ireland (NI) continue to be covered by the EU BPR under the Northern Ireland protocol.

The North American situation

In the US, the FDA regulates over-the-counter (OTC) consumer products such as antiseptic hand rub and antibacterial soap. For consumer hand sanitizers, a monograph approach is used for three common active ingredients: benzalkonium chloride, alcohol (ethanol or ethyl alcohol) and isopropyl alcohol.

Consumer products using any of these ingredients at certain concentrations can make antimicrobial hand sanitizing claims without undergoing the FDA's rigorous New Drug Application process. Instead, compliant products follow the automated drug registration and listing system. In addition, the manufacturing facilities must register with the FDA and the final finished product must be manufactured under Current Good Manufacturing Practices (CGMP). While efficacy and safety information doesn't need to be submitted, manufacturers are required to have this data on file in case the FDA requests it at a later date.

Formulations containing an active ingredient other than the three specified require a New Drug Application.

In Canada, hand sanitizers intended for domestic or personal care use can be registered under the Canadian Antiseptic Skin Cleansers (Domestic/ Personal Use) Monograph. Alcohol-based products are classified as natural health products and receive market authorization via the Natural Product Number (NPN) application process whereas products containing other active ingredients (i.e. benzalkonium chloride, chlorhexidine gluconate, etc.) are considered non-prescription drugs and receive market authorization through the Drug Identification Number (DIN) application process. Regardless of the active ingredient, if a product is intended for food, healthcare or commercial use, then it is no longer monograph compliant and the application will require safety and efficacy data.

Additional considerations for hand sanitizers

Many hand sanitizers are alcohol-based. The flammability of the active substance (and potentially of the product) introduces additional regulatory factors surrounding safe storage and transportation. There are customs implications too.

Consumer safety issues also need to be accounted for. It may be necessary to add a bittering agent so the general public does not misuse the product and labeling needs to make it clear that it is not for consumption.

In France, regulated pricing was introduced for hand sanitizers in March 2020 following the price inflation that followed the surge in demand. At the time of writing, this is still in place.

Hand hygiene product labeling

All markets have their own stringent requirements for the labeling of hand hygiene products. In GB and the EU, this is largely dictated by a product's alignment with either cosmetic or biocidal regulations as well as Classification, Labeling and Packaging (CLP) regulations. Many aspects of the label and the product description need consideration, from font size to illustrations (such as pictograms or symbols) as well as the way information is presented. In the US, consumer-grade hand hygiene products are considered over the counter monograph products and must follow the associated labeling requirements. The products must show an efficacy of at least 3 log reduction, and manufacturers cannot list target organisms on the product label.

In Canada, hand sanitizers authorized via the monograph stream must comply with the strict labeling requirements specified in Health Canada's Antiseptic Skin Cleaner Monograph. This includes specific statements that must appear on the label such as cautions and warning statements, product use statements, directions for use, contraindications and risk statements, and warning statements.

Selling through online retailers

The rise of e-commerce via Amazon and other online retailers has opened new direct-to-consumer channels for manufacturers of hand hygiene products as well as secondary sellers and distributors. This has raised concerns surrounding product efficacy and safety since inexperienced sellers may be unaware of regulatory requirements surrounding labeling, registration and reporting.

In the US, some online retailers are encouraging sellers to educate themselves on federal responsibilities. In the UK, Amazon sellers are expected to ensure any product claims are compliant with applicable regulations and are not misleading. Any specific product claims related to COVID-19 are prohibited in the EU and the UK alike. Amazon's guidance to UK sellers reflects this[2]. Fundamentally, online retailers must follow the same rules as regular retailers. When it comes to regulations, there are no exceptions.

Consumer appeal and harmonization

Product shortages at the start of the pandemic underlined the benefit of developing products which meet the regulatory needs of multiple markets. When a single, uniform product can be sold around the world it streamlines manufacture and distribution, bringing better efficiency. But what about consumer expectations in different markets? Our research findings indicate that there is a high level of consistency.

For instance, all six countries we surveyed shared the same 'top five' factors of importance when purchasing hygiene products in response to COVID-19 (as shown in Figure 2 on page 5):

1. The desire to protect self and loved ones (65%)
2. That the product does what it's supposed to (57%)
3. Good price/value (44%)
4. Functional claims (38%)
5. Scientific evidence of effectiveness (35%)

These factors point towards an overall consumer desire for 'products that work' while offering good value. As mentioned earlier, we asked people about product claims that matter to them, and a clear majority in each of the six markets said 'effectively killing germs or bacteria' was important (77% on average). Knowing that products are manufactured to the highest safety standards was also important to more than half of consumers (54% on average) (Figure 3).

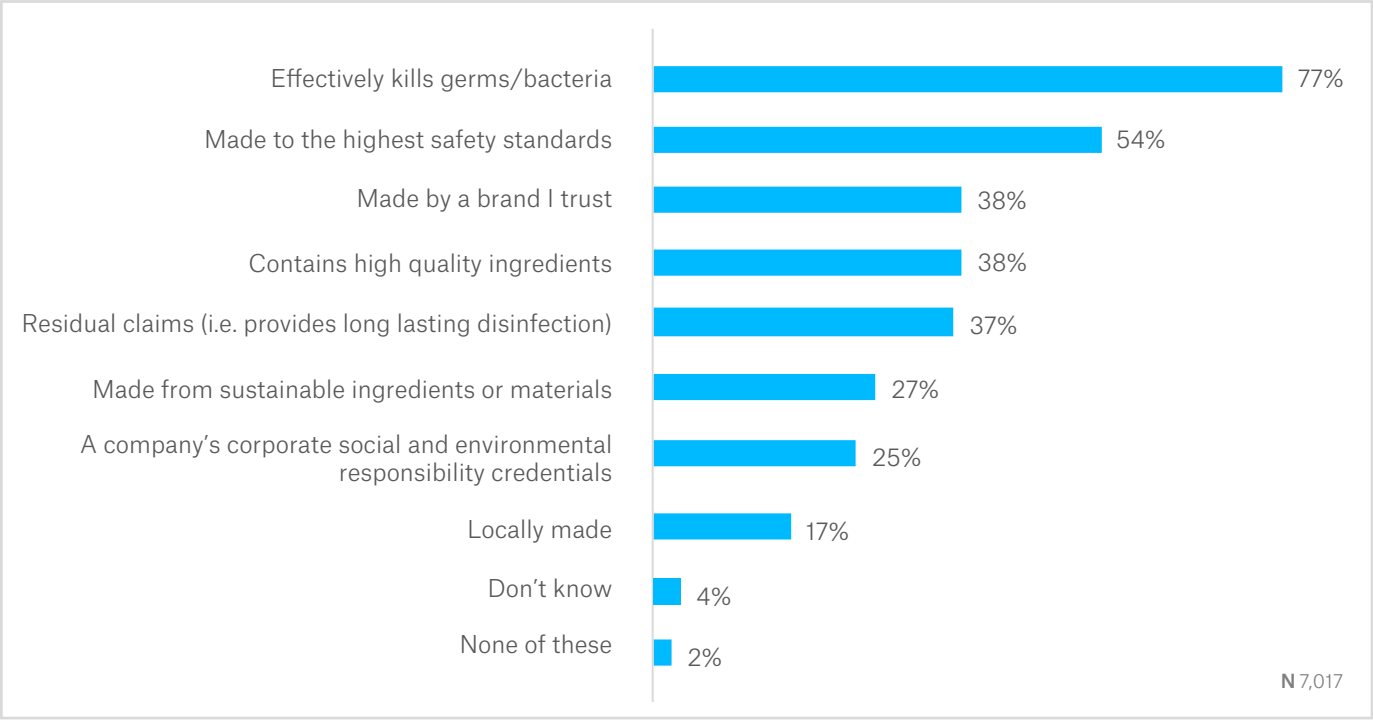


Figure 3: Findings related to the question "Which, if any, of the claims/features listed are important to you? (Please select all that apply)"

However, as Figure 4 indicates, most adults across the six countries feel that information surrounding effectiveness could be clearer and more accessible. Nearly three quarters (73%) rely on claims on packaging or in product descriptions to find products that are effective. Yet 67% say it is difficult to find this information, 72% say claims are often unclear and 81% would like the data substantiating claims to be more accessible.

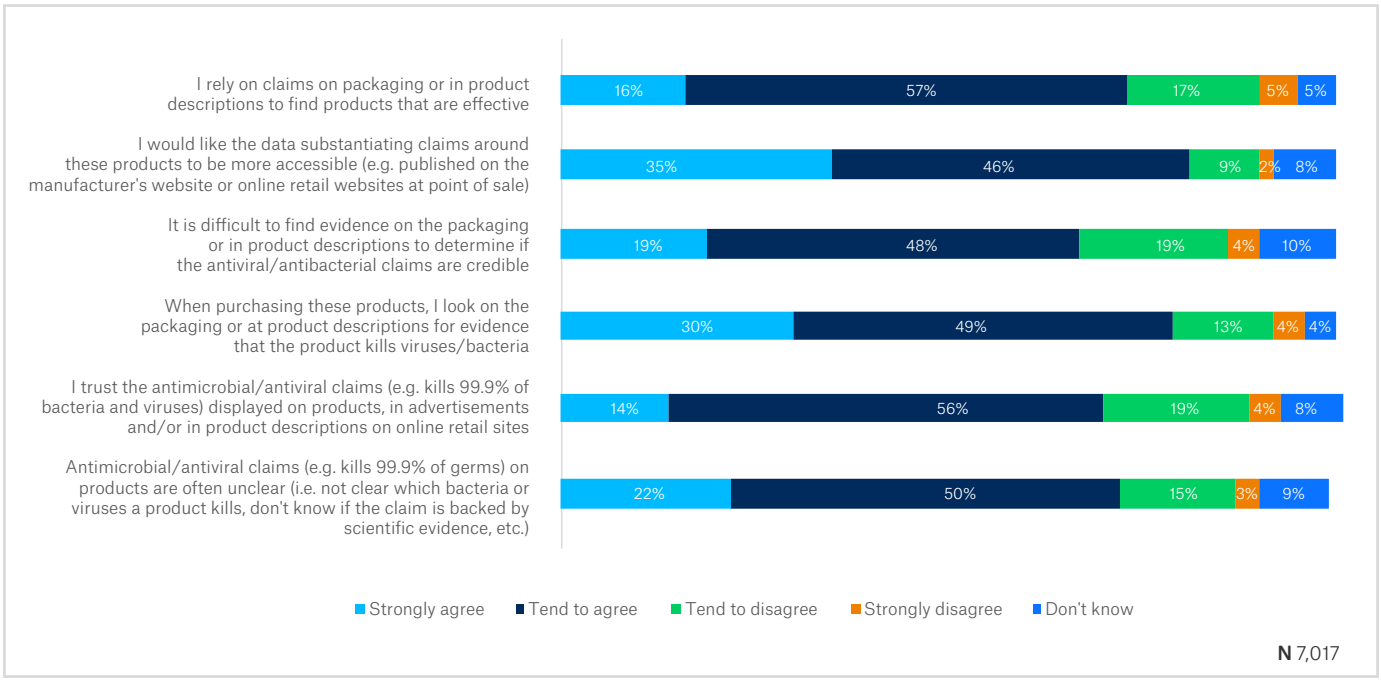


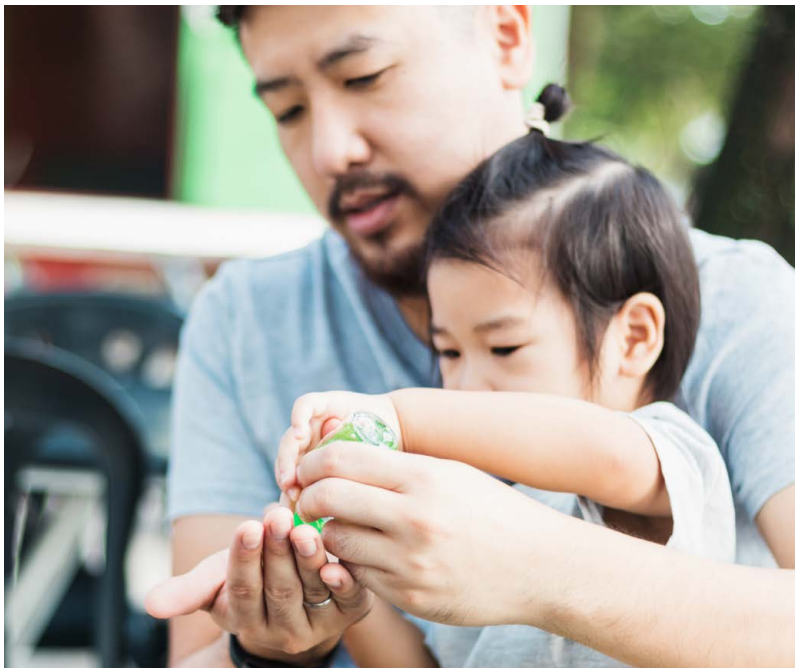
Figure 4: Findings related to the question "Still thinking thinking about any of the products mentioned previously that you have purchased for personal use because of coronavirus (COVID-19) (e.g. sanitizers, disinfectants, devices such as UV disinfection boxes, ozone sanitizing machines, foggers, etc.)... To what extent do you agree or disagree with the statements listed in relation to claims on these products?"

Final thoughts

Overall, our research indicates a broad synergy between consumer expectations and the global frameworks that regulate the production and sale of hand hygiene products. Clearly there are important nuances between markets, but the bottom line is that safety and efficacy are key.

With careful planning and expert insight, it is possible to navigate the complexities of global regulation in a systematic way. Getting this right unlocks opportunities to create products that satisfy compliance and hold consumer appeal in multiple markets.

Whatever direction the COVID-19 pandemic takes next, it's clear that consumer awareness of hand hygiene and its role in the prevention of illness has increased. Manufacturers that streamline production and product development stand to benefit from quicker routes to market as well as more cost-effective international operations.



How TSG can help

We offer a wide range of services and support in the US, Canada, EU and GB. This includes, but is not limited to:

- Full US state and federal registration and renewal service, including obtaining company numbers and establishment numbers and coordination with the EPA, Canada's PMRA and the EU BPR. Support with FDA OTC monograph drug registration and listing.
- A comprehensive pan-European infrastructure to meet the challenges presented by differing requirements across Europe with offices in France, Germany, Spain and Great Britain offering focused, local registration support.
- Support for non-EU countries including GB, Norway and Switzerland.
- Services include the development and review of antimicrobial/biocidal product claims and labeling, guidance on testing requirements, preparation and submission of registrations as well as a full cosmetic product regulatory service.

Notes

1. Distilleries and breweries pivot to producing hand sanitizer, Bloomberg, March 24, 2020 https://www.bloomberg.com/news/articles/2020-03-24/companies-revamp-to-make-hand-sanitizer-and-coronavirus-products
2. Prohibited Product Claims, Amazon Seller Central (UK) https://sellercentral.amazon.co.uk/gp/help/external/help.html?itemID=6GFTJ2TEFCTKN6Q&language=en_GB&ref=efph_6GFTJ2TEFCTKN6Q_cont_201743940

About TSG Consulting ¬

TSG Consulting provides companies with high quality regulatory and scientific consulting services.

We help clients worldwide address the technical and regulatory issues in taking their products to market in multiple jurisdictions. Our scientific expertise, regulatory knowledge and understanding of local nuances enable our clients to navigate the complex and ever-changing regulatory landscape across the globe.

We serve a number of key markets and industry sectors including agricultural, industrial, consumer, food and beverage, animal health, and medical. Our teams comprise scientists and regulatory experts – many of whom have previously held positions at regulatory agencies, departments, and in industry.

This combination of science, regulatory expertise and knowledge of how institutions and industry operate provides our clients with superior and well-rounded guidance. TSG Consulting has offices in France, Germany, Spain, UK, USA and Canada. TSG is a Science Group (London listed) company.

info@tsgconsulting.com

www.tsgconsulting.com

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- Regulatory & Compliance: helping clients in highly regulated markets to launch, market and defend products internationally, navigating the frequently complex and fragmented regulatory ecosystems.
- Frontier Smart Technologies: designing and manufacturing chips and modules for the DAB/ DAB+ radio markets with 80% market share (excluding the automotive market).

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