



Introduction

There is no doubt that the recent COVID-19 pandemic has spurred the market for hand sanitizer. The demand for hand hygiene products is higher than ever before and has been exceeding the worldwide supply due to the sudden global outbreak of the virus. To ensure reliability and safety around hand sanitizer products, there are a number of regulatory requirements when it comes to the alcohol-based substance, making sample testing a crucial part of the manufacturing process.

Outlook in The Global Market

Sales of hand sanitizer globally reached USD 1.2 Bn in 2019¹ and since the SARS-CoV2 pandemic record demand has seen that figure grow exponentially with sales reaching over USD 1.4 Bn in 2020². North America represents the largest market share followed by Europe. Back in the first quarter of 2020, retail sales exploded with up to a 495% change in volume sales compared to the previous year, according to Nielsen³ and most forecasts predict continued growth up to at least 2025.

Sanitizer is dominated by alcohol-based product varieties, but non-alcohol-based products also form a niche in the market. It can be produced in the form of liquid, gel, foam or spray. The market is dominated by gel as the most preferred product type and this holds by far the largest market share.

Top 5 Analytical Tips

1. Develop a testing process either in-house or with a trusted laboratory provider who can process samples swiftly so that supply chains are not held up.
2. Ensure hand sanitizer is kept physically separate to your other end-products to eliminate cross contamination during manufacture and QA/QC testing stages.
3. Ensure you have a reliable and fast technique to quantify ethanol and isopropanol content compounded according to WHO and FDA-approved formulations.
4. Use an adulterant screen to detect methanol down to 300 ppm, to secure sample safety and easily fulfilling FDA requirements.
5. Get a workflow driven intuitive software with your testing equipment, which includes starter calibration and produces instant on-screen results.

Health and Safety Meets Market Pressures

Producers face many challenges; some have switched from producing products like alcoholic beverages or cosmetics and need to understand the regulatory and Health and Safety implications. Failure to understand and follow safe ingredients testing, contamination guidelines and label claim recommendations, risks human health and brand value. In addition, high global demand for input chemicals including disinfectants like Chlorine, combined with disruption to international supply chains have led to stock shortages and price inflation.

Lab Testing Processes and Supply Chain Needs

Before the pandemic, testing labs like Good Cat based in Florida, were engaged in a very broad range of product testing. In the case of GoodCat Laboratories, the pandemic led to a sudden, steep increase in hand sanitizer testing, so they learned a lot in a short amount of time. As Brenna Boss, the Lab Manager at GoodCat says, "Before the pandemic, we didn't have a need to test hand sanitizer". In GoodCat's case, it all started with one savvy customer, who saw the opportunity and decided to switch some of their manufacture to hand sanitizer production. Batches of up to 20 samples a day are processed in the lab. Often these can arrive with the tanker and vials of the samples taken directly from it so that testing can take place immediately, results are verified, and the product can proceed quickly on its supply chain. The samples or vials taken into the lab are then tested for purity and composition. The customer needs this to happen as swiftly as possible so they can pack and ship it out for retail.

Analytical Solutions Align with FDA/WHO

GoodCat considered a range of analytical tools but decided to install a Hand Sanitizer Analyzer from PerkinElmer, an FT-IR on the Spectrum Two platform. The compact desktop instrument allows for rapid sample throughput and has integrated workflow driven software for instant on-screen results.

The FDA (US Food & Drug Administration) and WHO (World Health Organisation) scrambled to issue safety advise to the market in early 2020. The FDA created a guidance document⁴, based on formulations that are recommended by the WHO for the compounding of certain alcohol-based hand sanitizer products to cope with shortfalls⁵. These are the ideal levels recommended by the WHO:

- Hydrogen Peroxide (0.125% v/v)
- Ethyl alcohol (80% v/v) OR Isopropyl alcohol (75% v/v)
- Sterile or distilled water (Remainder of volume)
- Glycerol (1.45% v/v)

The content and type of alcohol are the key parameters that must be considered in compounding. It has also been established that hand sanitizer with an alcohol concentration that is less than 60% (v/v)⁶, is less effective and could leave the user at higher risk of infection.

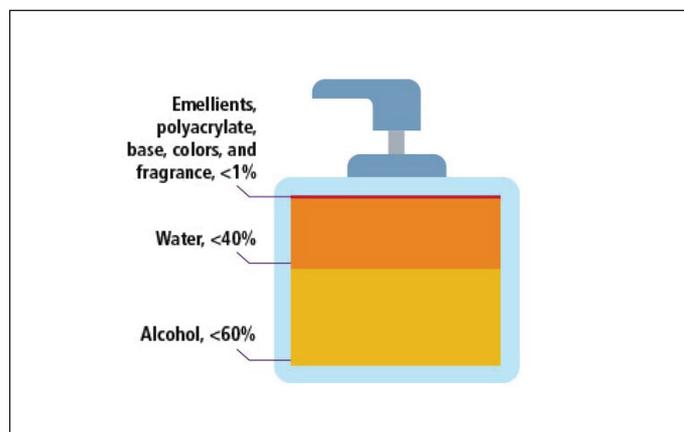


Figure 1. Alcohol concentration that is less than 60%, is less effective and could leave the user at higher risk of infection

Dangers in Methanol

Ethanol or Isopropyl Alcohol (IPA) in the correct concentrations, are safe to use. However, an increasingly important issue during the COVID-19 outbreak has been the discovery of methanol in some hand sanitizers. There have been instances of hand sanitizers that have partial or complete methanol content. In just one month, July to August 2020, the FDA issued warnings against using 130 different brands of hand sanitizer⁷, due to methanol contamination and the list continued to grow.

Together with PerkinElmer's Adulterant Screen™ algorithm, IR spectroscopy can be utilized as a screening tool for the detection of methanol in hand sanitizer. It can detect methanol contamination down to 300 ppm (0.03%)⁸, far exceeding the limits needed to adhere to FDA guidance (630 ppm). Spectrum Touch software enables this analytical step to be included in a one-click solution for establishing both the presence of methanol and alcohol concentration.

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References

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"At GoodCat Analytical batches of up to 20 samples a day are processed in the lab"



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