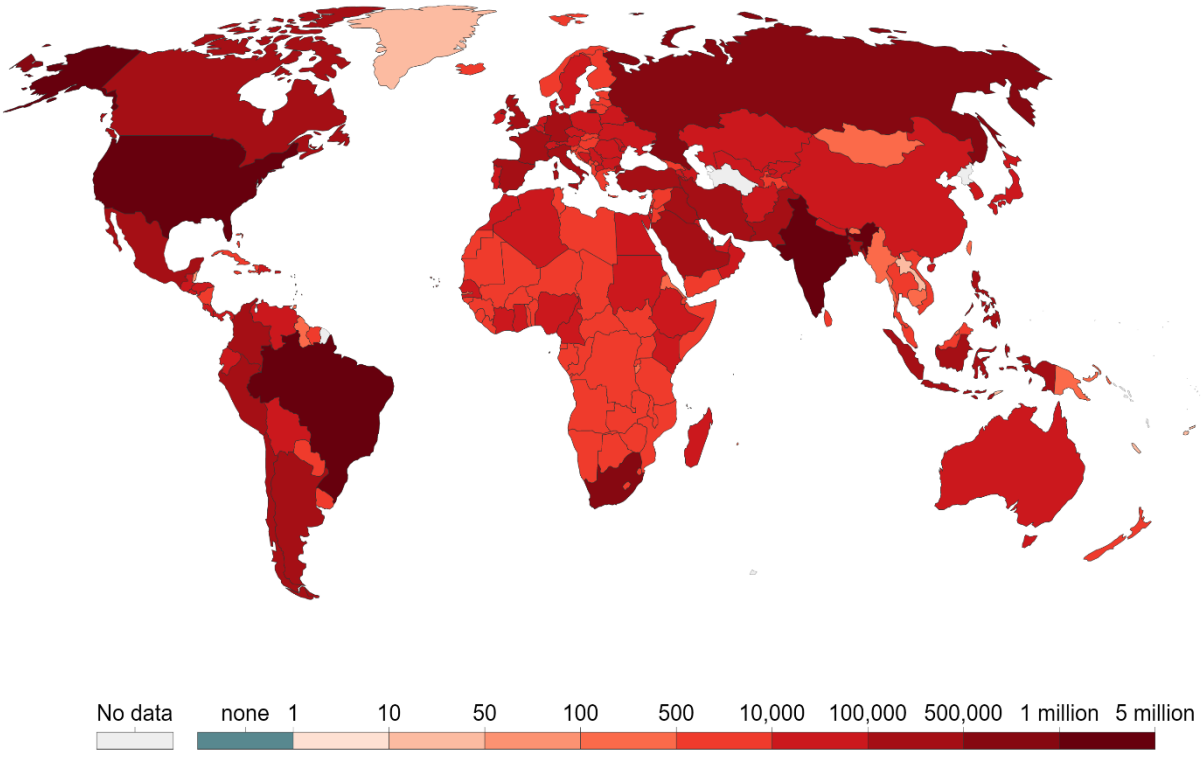
Dragon Sourcing

Your Tailored Approach to Emerging Markets

Sanitizer & Disinfectants during Covid-19

A Brief Study

Newsletter VII



Covid-19 cases by 3rd August, 2020

August 2020

Coronavirus pandemic has already crossed 18.4 million cases globally.

No vaccine or medicines are yet invented to break off this pandemic.

One and most common way adapted all over the world to protect self from this deadly virus is to repeatedly wash hands with soap or sanitizer and keep the surroundings clean using disinfectants.

Regarding skin reactions, Hand rub with alcohol-based solutions are better tolerable than hand washing with soap and water. But if hands are visibly soiled then soap and water are recommended.

This increased sales and demand of sanitizers and disinfectants dramatically, worldwide.

In order to cope up with surging demand, WHO has recommended two alcohol-based hand rub formulations for local production.

FORMULATION 1	FORMULATION 2
Ethanol 80% (v/v)	Isopropyl alcohol 75% (v/v)
Glycerol 1.45% (v/v)	Glycerol 1.45% (v/v)
Hydrogen Peroxide 0.125% (v/v)	Hydrogen Peroxide 0.125% (v/v)
Distilled water 18.425% (v/v)	Distilled water 23.425% (v/v)

(Above mentioned are the final concentrations of the formulations.)

Many local manufacturers and pharmacies are already using theses WHO formulations, following the guidance available on official WHO website.

For healthcare settings, Centers for Disease Control and Prevention (CDC) recommends using alcohol-based hand rub (ABHR) with ethanol more than 60% or isopropanol more than 70%.

CDC recommends use of EPA-registered household disinfectant and has issued List N: Products with Emerging Viral Pathogens AND Human Coronavirus claims for use against SARS-CoV-2 (containing 469 entries with latest update on 30th July 2020).

FDA Classification for Disinfectants

I. Chemical/Physical Disinfectant devices:

Classification Regulation	Device Type	Product Code	Device Classification
21 CFR 876.1500	Cleaning accessories for endoscope	FEB	II
21 CFR 880.6885	Medical devices sterilant	MED	II
21 CFR 880.6992	Medical devices disinfectors	MEC	II (exempt from premarket review unless indicated for high level disinfection or for use on endoscopes and accessories)
21 CFR 880.6992	Medical devices cleaners	MDZ	II
21 CFR 892.1570	High level disinfection reprocessing instrument for ultrasonic transducers, mist	OUJ	II
21 CFR 892.1570	High level disinfection reprocessing instrument for ultrasonic transducers, liquid	PSW	II

II. Ultraviolet (UV) Disinfecting Devices:

- Class II devices under 21 CFR 880.6600 (product code OSZ)
- Uses UVA or UVC light to produce a germicidal effect.

These devices are classified under medical device classification and require submitting a premarket notification (510(k)) submission to FDA before introducing them to in market.

FDA has issued Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency in March 2020. To receive a copy of guidance, one can send an email request to CDRH-Guidance@fda.hhs.gov

As declared by, Department of Health and Human Services (HHS), this policy is intended to be in effect on for the duration of public health emergency related to Covid-19.

Although, in normal condition, manufacturer or supplier must complete the premarket notification 510(k) submission process, as follow:

Manufacturer/Supplier must meet the requirement of 510(k) submission. Before marketing a device, each submitter must receive an order, in the form of a letter, from FDA which finds the device to be Substantially Equivalent (SE) and states that the device can be marketed in the US. This order “clears” the device from commercial distribution.

The 510(k) Submission Process

A 510(k) submission must be submitted in an electronic format (eCopy), should be sent to CDRH’s or CBER’s Document Control Center (DCC), which is available on eCopy Program for Medical Device Submissions

When the DCC receives the 510(k) submission, it assigns the submission a unique control number "510(k) number," or "K number", begins with K followed by 6 digits

If the proper user fee has not been paid and/or a valid eCopy has not been provided, then the DCC will email a Hold Letter to the 510(k) submitter, usually within 7 days of receipt of the 510(k). Submitter needs to resolve it within 180 days. If not resolved, it will be considered as withdrawn and has to submit new 510(k) FDA marketing clearance

After the Acknowledgement Letter is sent, the DCC routes the 510(k) to the appropriate ODE or OIR Division

Within 15 days of the receipt of the submission, the submitter will receive an electronic notification of the Acceptance Review result, which will: Identify name & contact information of FDA Lead Reviewer and Indicate the status

If the Lead Reviewer sends an AI (Additional Information) Request, the submission is placed on hold. The submitter must submit the response, with a valid eCopy, to the DCC within 180 calendar days of the date of the AI Request; including the submitter’s name; 510(k) number; identify the submission as Additional Information (AI) to the 510(k); date of FDA's request for AI and provide the requested information in an organized manner

When a decision is made, FDA will issue the decision letter to the submitter by email to the email address provided in the 510(k) cover letter. A 510(k) that receives an SE decision is considered "cleared." And submitter will be added in the 510(k) database, which is updated weekly.

FDA Process Timeliness

By Day 1
- FDA receives 510(k) submission

By Day 7
- FDA Sends Acknowledgement Letter OR
- FDA Sends Hold Letter if unresolved issue with User Fee and/or eCopy

By Day 15
- FDA conducts Acceptance Review
- FDA informs submitter if 510(k) is accepted for Substantive Review or placed on RTA Hold

By Day 60
- FDA conduct Substantive Review
- FDA communicates via Substantive Interaction to inform the submitter that the FDA will either proceed with Interactive Review or that the 510(k) will be placed on hold and Additional Information is required

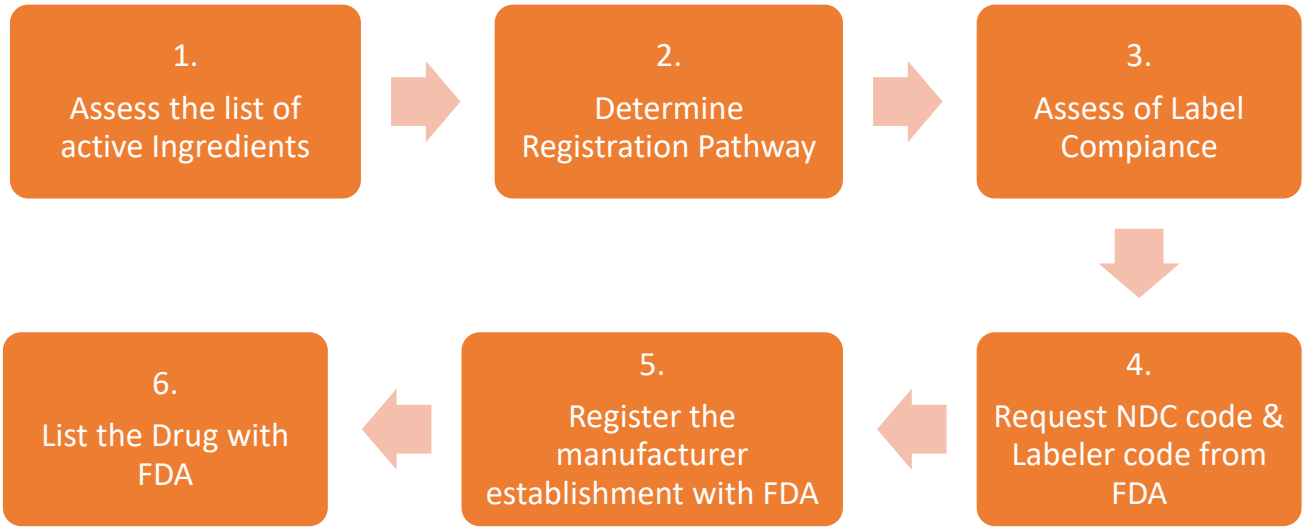
By Day 90
- FDA sends final MDUFA (Medical Device User Fee Amendments) Decision on 510(k)

By Day 100
- If MDUFA Decision is not reached by Day 100, FDA provides missed MDUFA Decision communication that identifies outstanding review issues

Hand Sanitizers under FDA

Hand sanitizers are regulated as over-the-counter (non-prescription) drugs by the U.S. Food and Drug Administration.

Hand Sanitizer Registration process with the FDA:



Generally, Hand Sanitizer FDA registration may take approximately 14-20 days working days. NDC (National Drug Code Directory) number may consume maximum time around 7-14 days, once requested with FDA.

To help meet the increased demand for hand sanitizers during the COVID-19 public health emergency, FDA has published three guidances. During this pandemic, entities which are currently not registered as drug manufacturers can register over-the-counter (OTC) drug manufacturers and make alcohol-based hand sanitizers, pharmacies and registered outsourcing facilities can compound the alcohol-based hand sanitizers and alcohol manufacturers can produce alcohol for sanitizers, by following the conditions outlined in the FDA guidances for industry.

The guidance copies are available on official FDA website, and can also be requested on mail to druginfo@fda.hhs.gov or COVID-19-Hand-Sanitizers@fda.hhs.gov

Also, FDA is testing the quality of different hand sanitizers used by the public and found many of them containing methanol, or wood alcohol – which is used to create fuel and not acceptable active ingredient for hand sanitizer, as they can be toxic when absorbed through skin and can be life threatening if ingested.

FDA is warning not to use hand sanitizer from the list of companies mentioned on https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-hand-sanitizers-consumers-should-not-use

EU Standards

Hand disinfectants (soap, gel, wipes) are considered Biocides in Europe.

The Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) replaced the Biocidal Products Directive (BPD) also known as the Biocides Directive is European Union Directive, (98/8/EC), and officially known as Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market.

The Biocides are classified as (according to Annex V):

Group 1
Disinfectants and general biocidal products

- Product-type 1: Human hygiene biocidal products
- Product-type 2: Private area and public health area disinfectants and other biocidal products
- Product-type 3: Veterinary hygiene biocidal products
- Product-type 4: Food and feed area disinfectants
- Product-type 5: Drinking water disinfectants

Group 2
Preservatives

- Product-type 6: In-can preservatives
- Product-type 7: Film preservatives
- Product-type 8: Wood preservatives
- Product-type 9: Fibre, leather, rubber and polymerised materials preservatives
- Product-type 10: Masonry preservatives
- Product-type 11: Preservatives for liquid-cooling and processing systems
- Product-type 12: Slimicides
- Product-type 13: Metalworking-fluid preservatives

Group 3
Pest control

- Product-type 14: Rodenticides
- Product-type 15: Avicides
- Product-type 16: Molluscicides
- Product-type 17: Piscicides
- Product-type 18: Insecticides, acaricides and products to control other arthropods
- Product-type 19: Repellents and attractants

Group 4
Other biocidal products

- Product-type 20: Preservatives for food or feedstocks
- Product-type 21: Antifouling products
- Product-type 22: Embalming and taxidermist fluids
- Product-type 23: Control of other vertebrates

Authorisation Process:

The authorisation of biocidal products takes place in two consecutive steps:

1. Active Substances

Such as Ethanol, propanol, chlorhexidine, chlorine, quaternary ammonium compounds, used in a biocidal product must be assessed positively for safety & efficacy.

- Assessments evaluations are to be completed by the Competent Authorities of the Member State (MSCA) or the European Chemical Agency (ECHA), and then approved by the European Commission for a specific Product Type (PT)
- According to Article 95 of the BPR, companies placing the active substance on the market needs to make sure either 'substance supplier' or 'product supplier' must be in the list of approved active substances and suppliers published by ECHA.

2. Biocidal Product containing Active Substance

Before being used or sold in the market, biocidal products must be authorised by Competent Authorities (MSCA or ECHA). And the active substance contained by it must be previously approved.

There are two types of biocidal product authorisation processes depending on the approval status of the active substance in it:

Pending approval for active substance

With subject to national registration granted by the relevant Member State, Biocidal products containing active substances which are currently in Review Programme can be made available and used in EU market.

For eg., ethanol-based hand sanitizer

Approved active substance

The biocidal product with approved active substance in Review Programme with specific product type, must be authorised according to the procedures and requirements mentioned in the BPR.

For eg., sodium hypochlorite-based hand sanitizer (chlorine released)

The national Competent Authority or ECHA can authorise a disinfectant if:

- The active substance is under review or approved for relevant PT
- The product is effective for its intended use(s)
- The product and its usage is safe for animal, human and environmental health
- Efficacy claims such as Antibacterial, Disinfectant, Fight germs, Kills 99% bacterial, etc. must have been supported by the testing

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