Report on Hand Sanitizer HAND SANITIZER BUSINESS IN NEPAL AND ITS SAFETY ISSUES



Prepared Centre for Public Health and Environmental Development (CEPHED) Kathmandu, Nepal, email: info@cephed.org.np

March 2021



POPPER PO



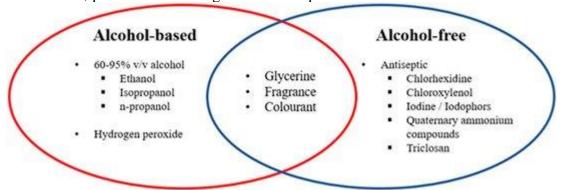
Report on Hand Sanitizer

HAND SANITIZER BUSINESS IN NEPAL AND ITS SAFETY ISSUES

What are Hand Sanitizers?¹

Hand sanitizer is a liquid, gel, or foam generally used to decrease infectious agents on the hands. In most settings hand washing with soap and water is generally preferred. Hand sanitizer is less effective at killing certain kinds of germs unlike hand washing, it cannot physically remove harmful chemicals. People may incorrectly wipe off hand sanitizer before it has dried, and some are less effective because their alcohol concentrations are too low. It is sometimes harmful because of containing some hard chemicals and/or not proper chemicals contained in it.

Hand sanitizer is now commonly used in hospitals, offices, public washrooms, restaurants and at home, places where using hand is still possible.



Medically the use of hand sanitizer is recommended for health concerns. The Center for Disease Control (CDC) recommends the use of sanitizing products in healthcare settings. Studies have shown the clear benefits of its use. The sanitizers decrease gastrointestinal sicknesses within the home and reduce the amount of illness in schools that use them. Thus it decreases the amount of absenteeism in the schools. However they recommend that the sanitizer being used contains at least 60% alcohol for it to be effective. Otherwise the product is simply moving the bacteria around your hands.

History of Hand Sanitizer ²

But while alcohol has been in use as an antiseptic since the <u>late-1800s</u> least, the exact origins of hand sanitizer are up for debate.

¹ 5 side effects of hand sanitizers you didn't know about (thehealthsite.com)

² The History of Hand Sanitizer | History News Network (hnn.us)

One version of the story points to <u>Lupe Hernandez</u>, a nursing student in Bakersfield, California in 1966, as the inventor of hand sanitizer after combining alcohol and gel for use by doctors in situations where they don't have time to access soap and warm water before treating patients.

However, a <u>recent investigation</u> by the Smithsonian Institution historian Joyce Bedi was unable to turn up any trace of Hernandez, or any evidence of a U.S. patent for hand sanitizer under that name from the 1960s.

There's also Sterillium, which the German company <u>Hartmann claims</u> was "the world's first marketable alcohol-based hand disinfectant" when it hit European shelves in 1965. It's made with glycerin and 75% alcohol.

Still, others trace modern hand sanitizer back to Goldie and Jerry Lippman, the married couple that <u>developed a waterless hand cleaner</u> in 1946 for rubber plant workers who previously used harsh chemicals like kerosene and benzene to remove graphite and carbon black from their hands at the end of their shifts. The product, which they called Gojo (a portmanteau of their names) is a <u>mix</u> of petroleum jelly, mineral oil and less than 5% alcohol that's <u>still used today by automechanics</u> and other workers to clean off substances like grease and oil.

The Lippman's mixed their first batches of Gojo in a washing machine in the basement of Goldie's parents' Akron, Ohio home, where the couple was living at the time, according to <u>The New Yorker</u>. They put the resulting product in pickle jars and sold it out of the trunk of their car.

Over the ensuing decades, Gojo continued selling their products as industrial cleaners. Then, in 1988, the company invented the hand gel Purell, which consists of 70% ethyl alcohol as its primary ingredient, along with propylene glycol. While Purell is now the world's best-selling hand sanitizer, it took some time for stores to carry the product that most everyday customers weren't really asking for. As such, Gojo did not release Purell onto the consumer market until 1997.

Hand Sanitizer Market Overview:

The Global Hand Sanitizer Market size was valued at \$919 million in 2016 to reach \$1,755 million by 2023, and is anticipated to grow at a CAGR of 9.9% from 2017 to 2023. Hand sanitizer is an antiseptic solution, which is used as an alternative to soap and water. It is used to prevent the transmission of infection, which is majorly caused through hand transmission, further causing several diseases such as nosocomial food-borne illness and others.

Consumer inclination towards health & wellness and product innovation such as addition of fragrances in formulation of sanitizers are projected to boost the growth of the global hand sanitizer market. Furthermore, improvement in living standards, rise in health expenditure, increase in awareness about hand hygiene, and support from organization such as WHO, FDA, and others towards the need for sanitation augment the demand for hand sanitizers. However, health hazards associated with chemical ingredients are anticipated to hamper the market growth during the forecast period.

The prominent players operating in the global market have strategically focused on product launch as their key strategy to gain significant share in the market. The key players profiled in the report include Reckitt Benckiser Group, The Himalaya Drug Company, Procter and Gamble, Gojo Industry Inc., Henkel Corporation, Unilever Plc., Vi-Jon Laboratories Inc., Chattem Inc., Best Sanitizers Inc., and Kutol Products Company.



The report segments the global <u>hand sanitizer market</u> based on product, distribution channel, end use, and geography. On the basis of product, the market is classified into gel, foam, spray, and others. Gel hand sanitizers accounted for the maximum share in 2016. By distribution channel, it is divided into online store, departmental store, pharmacy store, and others. Depending on end use, it is fragmented into restaurants, schools, hospitals, household purpose, and others. Geographically, it is analyzed across North America, Europe, Asia-Pacific, and LAMEA. In addition, the report highlights various factors that impact the growth of the global hand sanitizer industry, such as key drivers, restraints, growth opportunities, and the role of different key players.



North America dominates the global hand sanitizer market, owing to high hygiene standards among the U.S. population. Moreover, Asia-Pacific is expected to witness the highest growth rate from 2017 to 2023, owing to increase in concern towards health and wellness. Furthermore, improvement in living standards and rise in disposable income are expected to boost the growth of the Asia-Pacific hand sanitizer market.



Gel-based hand sanitizers generated the maximum revenue in 2016, as they are easily available in the market and require lesser time to effectively eradicate germs as compared to spray and other sanitizers. However, foam-based hand sanitizers are expected to grow at the highest rate, owing to the fact that foam hand sanitizers immediately cling to hands while applying. In addition, foam

pumps are relatively smaller than gel or spray pumps, and hence provide a convenient option to the consumers.

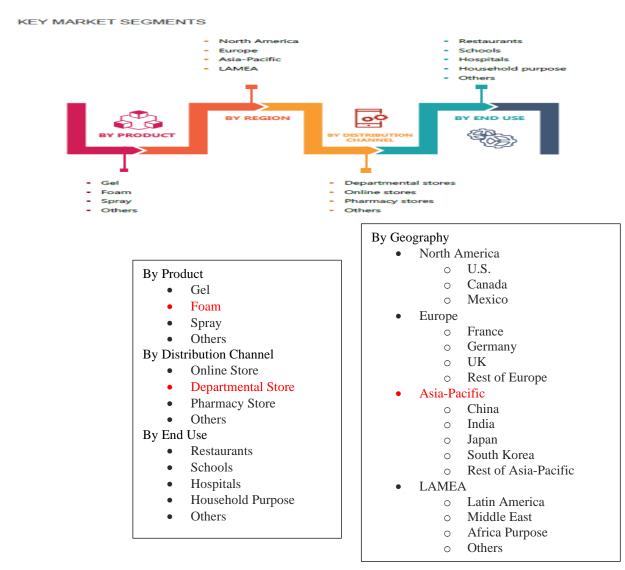


Departmental store accounted for the maximum revenue in 2016, as customers prefer to purchase from store such as super markets/hypermarkets. Furthermore, attractive discount policies offered by vendors' fuel the growth of departmental stores. However, online store registers the highest growth rate, owing to increase in penetration of mobile phones, rise in e-commerce sales, ease payment options, and attractive discounts as compared to stores. The key players profiled in the report are Reckitt Benckiser Group, The Himalaya Drug Company, Procter and Gamble, Gojo Industry Inc., Henkel Corporation, Unilever, Vi-Jon Laboratories Inc., Chattem Inc., Best Sanitizers Inc., and Kutol Products Company.

Key Benefits

- This report provides an extensive analysis of the current and emerging market trends and dynamics of the global hand sanitizer market.
- The market trend analysis for all the regions is conducted by constructing estimations for key segments between 2017 and 2023 to identify the prevailing opportunities.
- The report assists to understand the strategies adopted by the leading companies in the industry.
- This study evaluates competitive landscape of the hand sanitizer industry to understand the market scenario globally.
- Extensive analysis is conducted by key player positioning and monitoring the top competitors within the global market.

Hand Sanitizer Market Key Segments:



Hand Sanitizer Market, Size, Share & Industry Analysis 2022 (alliedmarketresearch.com)

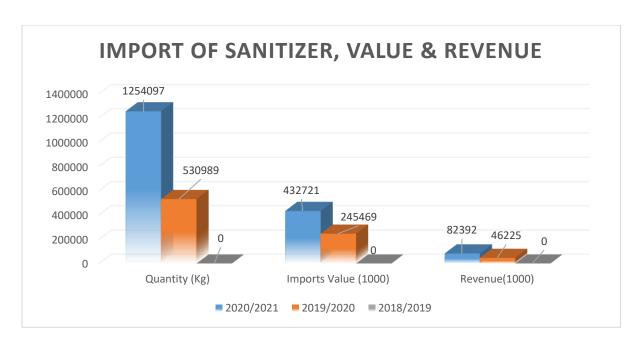
Sanitizer Market in Nepal

Before COVID-19 pandemic, it seems that Nepal is self-sufficient in fulfillment of its sanitizer demands from its domestic production. Nepal use to produced sanitizer of worth up to NRP 50000000 (US\$ 427350) in normal condition has reached over NRP 200000000 (>1.7M US\$) domestic products due to spread of COVID infection. In addition to this, the import of sanitizer has gone very high from zero till July 2019. According to Department of Custom (DOC), Ministry of Finance import record a total of 530989 Kg of Sanitizer was imported within the period of Mid 16 July 2019 to 15 July 2020. The importation amount has been more than doubled of the previous year import of sanitizer just within 5 months period of 2020 (16th July 2020 to 15th December 2020). Almost similar trend in imports value and revenue has been seen in case of sanitizer importation. Disinfectant importation become Zero in the year 2020 while other disinfectants were Zero in 2018/19 as clearly tabulated in the table given below.

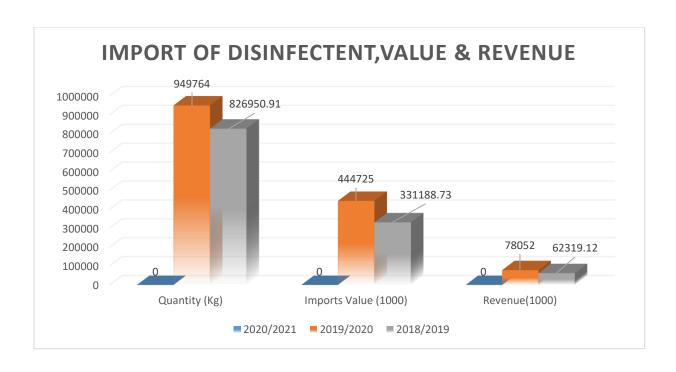
	Sanitizer			Disinfectants			Other Disinfectants		
Import of	(HS Code 338089410)			(HS Code 338089400)			(HS Code 338089490)		
		Imports			Imports			Imports	
Physical	Quantity	Value	Revenue	Quantity	Value	Revenue	Quantity	Value	Revenue
Years*	(Kg)	(1000)	(1000)	(Kg)	(1000)	(1000)	(Kg)	(1000)	(1000)
2020/2021**	1254097	432721	82392	0	0	0	494188	200365	37631
2019/2020	530989	245469	46225	949764	444725	78052	133538	53100	10047
2018/2019	0	0	0	826950.9	331188.7	62319.12	0	0	0

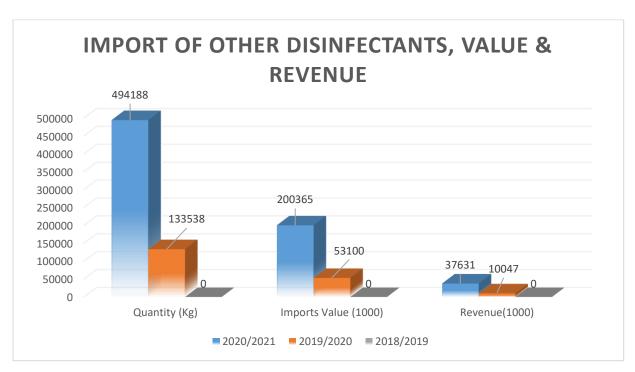
Source: Department of Custom, Import Data 2018, 2019 and 2020

NOTE: * Physical year start from Mid of July to Mid of July next year as per the Nepali calendar years, ** 5 Months (16 July 2020 to 15 December 2020 data only)



These sanitizers and disinfectants have been imported from different countries including Bangladesh, China, India, Italy, Japan, Korea, Malaysia, New Zealand, Singapore, United Arab Emirates, Australia, Germany, Ireland, Israel, Japan, Mexico, Singapore, Swaziland, Thailand, Turkey, and United State of America etc.





Government of Nepal Initiatives to regulate Hand Sanitizer:

Following the COVID-19 fallout, the demand of hand sanitizers has skyrocketed and almost everyone use sanitizers frequently to avoid the novel coronavirus infection but frequent use of hand sanitizers may cause serious side effects on a longer run, Nearly 45 per cent of 21 hand sanitizers tested in Kathmandu are completely ineffective to kill any virus, revealed a microbiology study conducted by the National Academy of Science and Technology (NAST), not meeting the Government of Nepal Standard (Annex 3). It is

feared that it will take years, even decades, to find out the side effects of the excessive use of hand sanitizers. Use of soap and water is comparatively better to clean our hands."

The retail stores and pharmacies are selling hand sanitizers in massive number after the outbreak of the COVID-19. The concerned agencies should monitor and regulate both domestic and imported products. Suggesting the consumers to minimize the use of hand sanitizer, it has been advised that washing hands with soap and water to the extent possible.

The Department of Drugs Administration (DDA) is the concerned agency to regulate and monitor the hand sanitizer products. The DDA had issued a notice for the first time around six months ago to register the sanitizer company within three months. The DDA again issued the notice to register the company three months after it had issued the first notice.

Center for Public Health and Environmental Development (CEPHED), said that the guidelines to make hand sanitizers should be fixed by the DDA, as it is the single concerned agency of the nation responsible to monitor and regulate the products available in the market by having comprehensive and regular market monitoring with the Director General of the DDA.. "Nepal has been importing hand sanitizers from Bangladesh, China, India, Italy, Japan, Korea, Malaysia, New Zealand, Singapore, and United Arab Emirates among others in big quantities. DDA has to check the standards of these imported hand sanitizers and demanded for the same. Indicating the absence of high standard laboratory facility to conduct scientific study, CEPHED also ask with the government to develop the standards laboratory facilities as well.

CEPHED keep follow up its letter written to the Department of Drug Administration (DDA) DDA on 6th September 2020 to regulate the sanitizers increasingly imported, produced and used in Nepal to cope with the ongoing COVID 19 Pandemic raising the issues of highly toxic substance like Methanol contained in them and might cause different health impacts to the consumer. CEPHED had formally requested to find out the actual status of the sanitizer in Nepal, make the result public and bring these products under strict regulation of DDA.

Research on Hand Sanitizer issues potentially contaminated with toxic substances as well as not meeting the Government of Nepal Standards. Based on a result of study opened publicly by the Indian Consumer Groups in India. Nearly 50 per cent of 122 hand sanitizers tested in Mumbai and Thane are adulterated according to a scientific study conducted by the Consumer Guidance society of India (CGSI). CEPHED Nepal has raised this issues with the Government of Nepal, Ministry of Health and Population (MOHP) and its Department of Drug Administration (DDA).

Responding to the CEPHED campaign, Government of Nepal, Ministry of Health and Population (MOHP), Department of Drug Administration (DDA) has carried out massive testing of hand sanitizers and so far banned some 26 Hand Sanitizers of national and international products/brands marketed in Nepal.

Responding to this, DDA has taken swift action to call for registration of all sanitizer producing company to DDA, issues a standard for the sanitizer and market monitoring including collecting and testing the sanitizer samples. They have also initiated to take action to call back of such counterfeit products from the market and do more comprehensive and large market monitoring

and testing for all such products exist in the market. Massive media coverage on this advocacy campaign were achieved.

Department of Drug Administration (DDA) has also banned the sale and distribution of hand sanitizer produced by six companies. The Department banned the sale and distribution of sanitizer produced by six companies after methanol was found mixed in the sanitizer in course of recent market monitoring carried out by the Department. Methanol is harmful for human health.

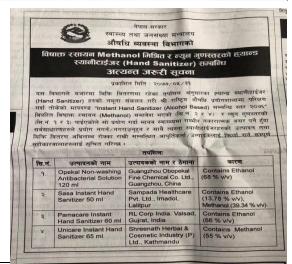
80 percent of methanol was found in 50 ml and 88 percent methanol in 500 ml sanitizer produced by Sita Herbal Sunsari. Similarly, methanol was found in the sanitizers produced by Makalu Herb of Sunsari, Sunima Ayurveda Company in Morang, MK Herbal of Lalitpur and Galaxy Dental and Surgical located in Morang. All these six brand of sanitizers has been banned in Nepal.





यस विभागले वजारमा विकिवितरणमा रहेका तपसिल अनुसारका ह्यान्ड स्यानीटाईजर (Hand Sanitizer) हरूको नमूना संकलन गरी श्री राष्ट्रिय जीपिछ प्रयोगशालामा परीक्षण गर्वा तोकेको मापदण्ड "Instant Hand Sanitizer (Alcohol Based) सम्बन्धी स्तर २०७६: विपरित विपाक्त स्सायन (Methanol) समावेश भएको तथा मापदण्ड विपरितका समिश्रण पाईएकोले मानव स्वास्थ्यमा गर्भार करात्मक असर पार्ने हुँदा सर्वसाधारणहरूले प्रयोग नगर्न/नगराउनुहुन र साथै त्यस्ता स्यानीटाईजरहरूको उत्पादन तथा विकि वितरण अभिलम्ब रोक्का राख्न सम्पूर्ण सरोकारबालाहरूलाई सचित गरिन्छ।

तपशिलः				
S. No.	Name of the product	Mfg. Date	उत्पादक/Repack गर्नेको नाम र ठेगाना	कारण
1.	Herbaltree Hand Rub 500 ml (B.N.273)	Aug-2020	Shivika Cosmeceuticals India Pvt Ltd, Pantnagar, Uttarakhand, India	Contains Methano (62% v/v)
2.	KUM Hand Sanitizer 5 Lit. (B.N.03)	Mar-2020	Repacked By: R. Chemical & Packaging Industries, Parsa, Nepal	Contains Isoporpy Alcohol (25 % v/v)
3.	Clean Hand Sanitizer 5 Lit (B.N.03)	Mar-2020	Repacked By: R. Chemical & Packaging Industries, Parsa, Nepal	Contains Methanol (8% v/v), Ethanol
4.	KUMKUM Instant Hand Sanitizer Gel 500 ml (B.N.01)	July-2020	Kumkum Herbal Industries Pvt. Ltd., Banepa, Neapl	Contains Methano (52% v/v)
5.	Instant Hand Sanitizer Gel 5 Lit (B.N.01)	Aug-2020	Kumkum Herbal Industries Pvt. Ltd., Banepa, Nepal	Contains Methano (72% v/v)
6.	Instant Hand Sanitizer Original, 1 Ltr. (B.N. OA-08)	Jun-2020	Om Arogya Healthcare Pvt. Ltd., Mahalaxmi-4, Imadol, Lalitpur, Nepal	Contains Methanol (7. % v/v)
7.	Sadhana Instant Hand Sanitizer, 5 Ltr. (B.N. 05)	Aug-2020	Sadhana Suppliers, Kathmandu, Nepal	Contains Methanol (4 % v/v),
8.	Drone Hand Sanitizer, 500 ml (B.N. 05) Yellow Colour	Sep-2020	Kalika Soap and Chemicals Pvt. Ltd., Kathmandu, Nepal	Contains Methanol (3: % v/v), Ethanol (9% v/v), Isopropyl Alcoho (31 % v/v), pH: 9.51
9.	Drone Hand Sanitizer, 500 ml (B.N. 05) Colourless	Sep-2020	Kalika Soap and Chemicals Pvt. Ltd., Kathmandu, Nepal	Contains Methanol (3: % v/v), Ethanol (10% v/v), Isopropyl Alcoho (32 % v/v), pH: 9.45



Department of Drug Administration (DDA) Notice 20 th November 2020,					
Sale, distribution of products of six hand sanitizer companies banned					
Name of the	Manufactures` Name and Address	Reason of banned			
Products					
 50ml Sanitizer 	Sita Herbal, Sunsari	contained 80 per cent of methanol			
2. 500 ml Sanitizer	Sita Herbal, Sunsari	contained 88 per cent of methanol			
3. Sanitizer	Makalu Herb of Sunsari,	Contain excess Methanol			
4. Sanitizer	Sunima Ayurveda Company in	Contain excess Methanol			
	Morang,				
5. Sanitizer	MK Herbal of Lalitpur	Contain excess Methanol			
6. Sanitizer	Galaxy Dental and Surgical, Morang	Contain excess Methanol			
• https://www.ficcalpanal.com/2020/11/20/2222/hand.capitizer.of.civ.more.companies					

: https://www.fiscalnepal.com/2020/11/20/2333/hand-sanitizer-of-six-more-companies-banned/#ixzz6o3YtmWHI

List of actions taken by Government of Nepal to regulate substandard hand sanitizers

S.No.	Dates	Actions taken
1	March 20, 2020	Arrangement of Sanitizer Production, Import, Export, Sales and
		Distribution
2	2076/12/09 BS	DDA issue a notice to register all company interested to produce
	22 March 2020	Hand Sanitizer within 3 months
3	2076/12/10 BS	DDA issue the Standards of Hand Sanitizer for only Alcohol based
	23 March 2020	Sanitizers.
	2076/12/26 BS	DDA issue a public notice not to produce, import, purchase, sale
	8 April 2020	and distribution of substandard sanitizer not meeting the standard
4	2077/02/09 BS Issues Notice for applying for Import license of Ethano	
	22 May 2020	material for Sanitizer
5	2077/3/22 BS	DDA extend the date of registration of company by another 3
	6 July 2020	months
6	Sept. 2020	DDA carried out series of market monitoring and testing of hand
		sanitizers.
7	SeptNov. 2020	DDA so far banned up to 26 different national and international
		brands of hand sanitizers
8	2077/5/27 BS	First 5 Brands of national Sanitizer Banned
	12 Sept. 2020	
9	2077/5/31 BS	Second 4 Brand of Sanitizer Banned India, China, Nepal
	16 Sept. 2020	
10	2077/6/12 BS	Third 9 Brands of inter/national Sanitizer Banned
	28 Sept. 2020	
11	2077/08/05 BS	Fourth 6 Brands of inter/national Sanitizer Banned
	20 Nov. 2020	

Hand sanitizer Standard of Nepal

Table 1 — Requirements for Instant Hand Sanitizer

S. No.	Characteristic Ethyl alcohol content or Isopropyl alcohol content	Requirement 70% to 80%v/v		
		6 - 8		
2.	pH	≥ 5 log reduction within 1 minute		
3.	Microbicidal activity	iding Gluconate content 0.5%v/v		

Hydrogen peroxide content as H₂O₂ 0.125%v/v or Chlorhexidine Gluconate content 0.5%v/v may be used.

WHO Guidelines for Composition of Sanitizers:

With a view to safeguard the interests of the general public and to maintain the quality of sanitizers brought in the market, the WHO has recommended a certain composition of the sanitizers. As per the Applicable on the India, hand rubs with optimal antimicrobial efficacy usually contain 75 to 85% ethyl alcohol/ ethanol, iso- propanol, or a combination of these products. Therefore the formulations advised by WHO either contain 75% v/v isopropanol or 80% v/v ethanol.

Conclusion

Responding on our research based advocacy and working with DDA, MOHP, and Government of Nepal has found to be active and taken numbers of initiatives and control measures to regulate the sanitizers not only of domestic products but also imported products. We have also raised the issues of substandard and toxicity associated with the humidifiers and disinfectants with the high hope of getting regulated by the Government of Nepal through its concerned Department of Drug Administration (DDA).