

Manufacturing of Hand Sanitiser

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To help reduce the spread of the Coronavirus, many companies with capacity are switching to the manufacture of hand sanitiser products. This introduces new risks that need careful management.



Manufacturing of Hand Sanitiser



Introduction

The coronavirus (COVID-19) pandemic that affected countries across the world in 2020 has led to many organisations switching manufacturing capacity to the manufacture of hand sanitiser products. Whilst supporting national efforts to reduce the spread of the disease, the manufacture of these products brings specific risks that need careful management to allow them to be manufactured safely. The World Health Organisation (WHO) recommend two specific formulations of hand sanitiser. *These use an alcohol (either ethanol or iso-propyl alcohol) as the main ingredient as it is the alcohol which is effective in rendering harmless, bacteria and viruses that may be present on hands. Both formulations blend the alcohol with a dilute solution of hydrogen peroxide and glycerol. These raw materials and the blends themselves present a number of challenges for their safe handling and storage.



Understanding the Hazards

Use of Flammable Liquids (alcohol)

The two different formulations use an alcohol solvent as their main ingredient. These alcohols are flammable liquids and poor storage and handling can lead to fire/explosion.

Ethanol (96%) has a flash point of 17°C.

Iso-propyl alcohol (99.8%) has a flash point of 13°C.

Hydrogen Peroxide Solutions

Both formulations recommended by the WHO use a 3% w/w solution of hydrogen peroxide. These solutions can cause irritation to the skin and damage to eyes in the event of an accidental splash. However, hydrogen peroxide is more commonly available in more concentrated solutions such as 30% w/w, and these more concentrated solutions provide further significant hazards. They can cause serious and painful skin burns and severe eye damage. They are also oxidising and will liberate oxygen gas when heated or involved in a fire, which can greatly accelerate the rate of fire growth and accentuate fire damage.

Glycerol

This non-hazardous substance is used within the formulation as an emollient. It will of course add to the general fire and would be consumed in any large fire event.

Hand Sanitiser Products

Manufactured hand sanitiser products are typically packaged within small plastic bottles. Both formulations recommended by the WHO have alcohol concentrations well above the minimum recommended levels of alcohol. The ethanol based product is 80% v/v ethanol and the iso-propyl alcohol based product is 75% v/v iso-propyl alcohol. At these concentrations the finished hand sanitiser products themselves are flammable liquids with flash points between 17-19°C.

*World Health Organisation: https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf

Reducing Risk of Fire

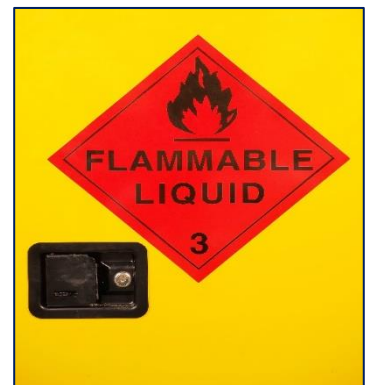
Risk Assessment

It's important that you review both your Fire risk assessment and any assessments required under the Dangerous Substances and Explosive Atmospheres Regulations 2002 (DSEAR). The storage and use of flammable liquids in particular can increase the risk of fire starting as well as greatly accelerating rates of fire growth and spread. As well as assessing risk controls to prevent fire starting, these materials may also impact available escape times from occupied areas and impede the effectiveness of any fixed fire protection systems already in place. Even the storage and use of plastic packing materials can greatly increase fire loads within your premises. Fully reviewing the impacts of these materials on your existing fire safety strategy will help ensure both lives and property are appropriately protected.

Storage of Flammable Liquids

The storage of flammable liquids (either raw materials or finished products) should be within a secure building/store separated from the main premises used for production. This building/store should ideally be of non-combustible construction and shade the stored materials from direct sunlight. Ventilation of the building is important at both high and low level. The design of the building/store should contain leaks and spills with the containment holding at least 110% of the volume of the largest container. Any lighting or electrical fittings within the building/store should be suitably specified for use in a Hazardous Area (Zone 2). The building/store should be adorned with a Flammable Liquids warning sign and appropriate fire extinguishers should be sited nearby. These can include both dry powder and AFFF foam extinguishers.

Should these manufacturing arrangements become a permanent aspect of your business, you should consider protecting these storage areas with an appropriately designed and specified fixed fire protection system. Depending on the size of the building/store this may include both gas deluge systems or a sprinkler system that has been specified to protect areas used for the storage of flammable liquids.



Handling and Dispensing of Flammable Liquids

It's important that flammable liquids are not dispensed within areas used for their storage. The necessary quantity of flammable liquids should be withdrawn from the store and taken to the production areas. It is good practice to keep only what you need within the work area, returning unused materials back to stores as soon as practicable.

Mixing vessels will ideally be enclosed stainless steel tanks. The level of liquid within the tanks should be continually indicated and the tanks should ideally be provided with ventilation/extraction to exhaust away any build-up of flammable vapours. The ability to inert the headspace within the tank with nitrogen gas provides an additional level of safety and can prevent a catastrophic explosion. The tank should be connected to an electrical earth at all times.

Transfer of the flammable liquids from drums to the mixing vessel should use a suitable pump. Pneumatically driven pumps can be best suited for this, ideally filling the vessel from the bottom upwards (dip-filling). The pumps should ideally shut-off automatically should the mixing vessel overfill. To reduce risks from electrostatic hazards, transfer hoses should be electrically conductive and the source drum should be grounded to the same earth as the mixing vessel.

LOSS PREVENTION STANDARDS

Electrostatic hazards require careful consideration in any plant design. Electrostatic sparks or brush discharges may have sufficient energy to ignite flammable vapours. A critical feature of plant design is that no metal components used in the conveying of flammable liquids are insulated or isolated from earth. You should also consider risks from static build-up on personnel who may handle flammable materials. Cotton rich clothing and safety footwear with an anti-static sole can reduce the build-up of static on a person.

Storage of Other Raw Materials

Both the hydrogen peroxide solution and glycerol should ideally be stored separately from the flammable alcohols. This is especially important if more concentrated hydrogen peroxide solution is being diluted to create the 3% w/w used for the mixture. If high strength concentrations of hydrogen peroxide that are classified as oxidising be stored awaiting dilution, these should be stored away from other combustible materials so far as is reasonably practicable.

Automated Filling and Packing Lines

Any equipment used for automated filling and packing of bottles of sanitiser should be suitably designed and specified for use with flammable liquids. Pneumatic filling equipment is normally specified for filling flammable liquids rather than electrically operated filling lines, and equipment should be included within DSEAR risk assessments. Any electronic controls and control panels within hazardous areas should be suitably specified/protected and typically use intrinsically safe equipment. The construction of such equipment protects not only the machinery itself but also those working in and around the machinery.

Once filled, the bottles of sanitiser are typically palletised. For onwards despatch and delivery, pallets are frequently wrapped in plastic film. Given the flammable nature of the products it is important that heated shrink wrap is not used. Under no circumstances should hand-held flame guns be used on these products.

Dealing with Spillages

In case of spillage it is important that you have pre-prepared emergency procedures, and that staff have a clear understanding of the risks of fire and have been trained in the correct spillage procedure.

Where spillages involve alcohols or the hand sanitiser product, small spillages can be dealt with using a proprietary spillage absorbent material or dry sand. Care must be taken to avoid accidental ignition of any flammable vapours released. Avoid using metal shovels to scrape up absorbent materials and ensure that staff clearing the spill are wearing suitable protective clothing.

For larger spills, deployment of foam from a fire extinguisher covering the surface of a spill can reduce the risk of accidental ignition of flammable vapours. As with smaller spills, proprietary absorbent materials or dry sand can be used to absorb the spill/foam mixture. Again, care must be taken in clearing up the spill to guard against accidental ignition and accidental contamination of staff.

The used absorbent materials should be placed in a suitable labelled container and disposed of via an authorised waste disposal route.

Controlling Other Sources of Ignition

The introduction of highly flammable materials into a workplace can make the elimination of fire inception risks **even more important**. **Smoking must be excluded from the premises. It's important that hot works are not** undertaken where flammable materials and packaging materials are used or stored. If such works are necessary, always ensure that the flammable materials and packaging are totally removed from the area where the hot works will be carried out. Always use a suitable permit to work system to manage such works. For more information please see Aviva's Loss Prevention Standard – [Hot Work Operations](#).

Be careful not to introduce ignition hazards into areas where flammable materials are stored and used. Portable heaters, electrical charging devices and other electrical equipment can be a hazard. Always refer to and check your Hazardous Area Classification completed as part of your DSEAR risk assessment to check which areas of the premises need to have restrictions on the types of electrical appliances you can safely use within them.

Fire Detection and Protection Systems

The introduction of flammable materials and large quantities of combustible packaging materials into a workplace makes it even more important that any fire event is detected as early as possible. Involvement of these materials in fires greatly increases rates of fire growth and spread, and early fire detection can give employees sufficient warning of the need to escape and can allow the Fire Brigade to be promptly summoned. All areas where hand sanitiser is made and where flammable materials are used/stored should be protected with automatic fire detection systems that meet BS 5839 – pt. 1. Given the increased risks of fire, a system specification that meets the requirements of either category L1 or P1 should be considered for these areas.

Any sprinkler systems that currently protect the areas that will be used to manufacture or store hand sanitiser will undoubtedly reduce fire risk, but their existing specification and design may not be suitable for control of a fire involving flammable liquids and materials. Should you plan to make hand sanitiser on a long term basis, you should make plans to review the design and specification of the sprinkler systems and if necessary, upgrade them to a suitable standard.

Safeguarding Employees

It is vitally important that employees working to manufacture hand sanitiser are adequately protected against personal injury and ill health. Risk assessments should be reviewed, taking into consideration new or altered risks that will be introduced as a result of these activities. Examples of new/altered risks include:

- Handling of substances hazardous to health: use of enclosed/pumped systems for the transfer of liquids to the mixing vessel can reduce risks of exposure. Well positioned Local Exhaust Ventilation (LEV) can capture vapours released from the mixing vessels and drums. Having reviewed your Control of Substances Hazardous to Health (CoSHH) assessments, Personal Protective Equipment (PPE) may also be considered in case of accidental splash/contamination. This may especially be considered when handling the hydrogen peroxide solutions. Rubber gloves and eye/face protection may be considered especially if more concentrated solutions are being diluted.
- Manual handling of drums and packaging: consider how you source the raw materials and whether employees may need to manually handle the containers. Where possible choose container/pack sizes that avoid the need to manually move or lift them to dispense them into mixing vessels. Use mechanical handling equipment and lifting aids wherever practicable.
- Workplace transport: give consideration to new/changed deliveries and collections from site. Also, whether routes taken by forklift trucks may alter to accommodate new storage areas/locations. Reduce risks from pedestrian/vehicle interactions so far as is reasonably practicable.

LOSS PREVENTION STANDARDS

- Slips trips and falls: spillages of glycerol and sanitiser product may make floors slippery and should always be cleaned thoroughly. Also give consideration to trip risks from trailed hoses where liquids are pumped into mixing vessels. It is recommended that safety footwear is worn by employees manufacturing the hand sanitiser.
- Dealing with emergencies: ensure that employees know what action to take in the event of an emergency situation. Scenarios that you should consider when reviewing your emergency procedures include:
 - A fire or explosion event involving flammable liquids
 - Chemical burns/irritation/eye contamination

Any employees who will respond to emergency situations must be trained and equipped to deal with any new situations that may be posed by the manufacture of hand sanitiser.

- Maintenance activities including breaking lines and working on contaminated plant: consider the risks that may present to maintenance workers who will work on the process plant used for the manufacture of sanitiser. In addition to the risks that normally present during maintenance, give particular attention to risks of accidental contamination if they need to break open pipelines. Also consider risks of fire and explosion should they need to work on or around plant that may contain flammable vapours.

Risk Users of the Products

Product Safety Legislation

It's important that you fully comply with laws governing product safety. The laws that apply largely depend on your intended use of the hand sanitiser:

- If the product is intended as a hand cleaner/moisturiser with a secondary microbial effect, this could be considered a cosmetic product and the requirements of the Cosmetic Products Regulations would apply.
- If the sole function of the product is to kill germs, disinfect or sanitise hands or prevent cross contamination, it may be considered a biocide. In such cases the requirements of the Biocidal Products Regulations would apply.
- If the product is labelled and marketed as specifically preventing disease or illness such as COVID-19, flu or other named illnesses, disease or pathogens, then it would be considered a medicinal product. In such cases Human Medicines Regulations apply.

Hence it is really important to consider how your product would be marketed and labelled. You should seek advice from regulatory bodies and seek formal advice on regulatory compliance including advice on formulation, packaging, labelling and quality control.

Formulations and Risk Assessment

It is recommended that formulations advocated by the WHO are used for the manufacture of hand sanitiser. Information can be found [here](#). It is important that these formulations are adhered to and that appropriate grade/purity raw materials are used in the manufacture. Despite some proprietary brands of hand sanitiser being coloured/scented, there is no need for this and any additions to the formulation need to be carefully risk assessed with testing completed by an accredited laboratory demonstrating no deleterious impacts of product efficacy as a result of their addition. Testing may also be needed to show no new allergenic skin irritation or increased toxicity as result of their addition. It is crucial that formulations have a final alcohol content above 70% v/v with higher concentrations being more effective.

LOSS PREVENTION STANDARDS

Sourcing Raw Materials

It is important that all raw materials are sourced from a reputable supplier who can provide a certificate of analysis demonstrating the raw materials meet the required specification and purity. If a certificate of analysis cannot be provided, you should consider arranging your own testing and analysis of the raw materials. Raw materials used should meet pharmacopeial grade requirement, being of high purity and absent from potentially harmful impurities. Care should be given to the source of water used in the formulation, and any water supplies used should be sterile and free from microbial contamination. Lastly, give consideration to the bottles that will be filled with hand sanitiser product and ensure they are sterile or can be made sterile before they are filled with product.

Quality Control

It is important you can demonstrate your products meet the necessary product specification. There are various methods that can be used to verify composition of the manufactured hand sanitiser. However, simple methods that can be used include using an alcoholometer for determining alcohol concentrations, whilst hydrogen peroxide concentrations can be measured using titration.

Product Labelling

Whichever regulatory framework that applies to your product will specify specific product labelling requirements. It is likely this will include some or all of the following information in addition to other requirements:

- **Manufacturers' details**
- Product description
- **Precautionary statements, e.g. "For external use only" or "Keep out of reach of children" or "Avoid contact with eyes" or "Flammable – Keep away from heat"**
- Instructions for use
- Date of manufacture and batch number
- Composition/ingredients

Labels should be clear and readable.

Notification of Interested Parties

You should consider who needs to know about your change in business activities. This may include:

- Alcohol licensing authorities and possibly HM Revenue & Customs
- Regulatory bodies for cosmetics, biocides or medicine depending on your intended product use
- Your insurance broker and current insurer
- Fire Brigade may want to know about the increased risk from flammable liquids. You may need to display a **warning sign at the site's entrance if more than 25 tonnes of hazardous substances are held on site at any one time**
- You may also need to check with planning authorities if you need a hazardous substances planning consent

Checklist

A generic Manufacturing of Hand Sanitiser Checklist is presented in Appendix 1 which can be tailored to your own organisation.

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Aviva Risk Management Solutions can offer access to a wide range of risk management products and services via our network of Specialist Partners who are reputable companies offering agreed discounted rates for Aviva customers.

For more information please visit:

[Aviva Risk Management Solutions – Specialist Partners](#)

Sources and Useful Links

- [Manufacture and supply of biocidal hand sanitiser products during the coronavirus](#) – Health and Safety Executive

Additional Information

To find out more, please visit [Aviva Risk Management Solutions](#) or speak to one of our advisors.

Email us at riskadvice@aviva.com or call 0345 366 6666.*

*The cost of calls to 03 prefixed numbers are charged at national call rates (charges may vary dependent on your network provider) and are usually included in inclusive minute plans from landlines and mobiles. For our joint protection telephone calls may be recorded and/or monitored.

Appendix 1 – Manufacturing of Hand Sanitiser Checklist



Location	
Date	
Completed by (name and signature)	

	Safe Storage of Flammable Liquids	Y/N	Comments
1.	Separate non-combustible building away from processing areas?		
2.	Building well ventilated and shades materials from direct sunlight?		
3.	Containment sufficient for 110% of largest container size?		
4.	Ignition sources including electrical fittings appropriate for hazardous areas (Zone 2)?		
5.	Appropriate warning sign fitted?		
6.	Sufficient fire extinguishers nearby at a marked fire point of a suitable type (including dry powder and foam)?		
7.	Stores protected by a fixed fire protection system?		

	Safe Handling of Flammable Liquids	Y/N	Comments
8.	Dispensing of flammable liquids is prohibited in storage areas?		
9.	Mixing and blending is carried out in enclosed steel tanks?		
10.	Measures in place to prevent the overfilling of mixing tanks?		
11.	Mixing tanks are either extracted and/or can be inserted with nitrogen?		
12.	All mixing vessels and dispensing drums can be connected to a common earth?		

LOSS PREVENTION STANDARDS

	Safe Handling of Flammable Liquids Cont.	Y/N	Comments
13.	Employees involved in manufacture are wearing appropriate clothing and footwear to guard against electrostatic discharge?		
14.	Filling lines are suitably specified and do not present sources of ignition?		
15.	Manufacturing and storage areas have been included within DSEAR risk assessments with hazardous areas specified and appropriately signed?		
16.	Electrical fittings and equipment within hazardous areas have been appropriately specified to reduce ignition risk and are suitable for the designated zone (e.g. Zone 0, Zone 1 or Zone 2)?		
17.	Filled bottles of hand sanitiser are not heat wrapped onto pallets?		

	Other Fire Hazards	Y/N	Comments
18.	Hydrogen peroxide solutions are stored in a separate fire compartment to flammable liquids?		
19.	There is a strict no smoking policy on site?		
20.	Hot works are prohibited in any areas where flammable liquids are being stored or used? Flammable liquids are completely removed from these areas before any hot works commences and all hot works are controlled using a suitable hot work permit?		

LOSS PREVENTION STANDARDS

	Fire Protection and Emergency Procedures	Y/N	Comments
21.	All areas where flammable liquids are handled or stored are protected by automatic fire detection systems?		
22.	All areas where flammable liquids are handled or stored are protected by appropriately specified fixed fire protection systems (e.g. sprinkler systems, gas deluge or automatic dry powder systems)?		
23.	Emergency procedures have been reviewed and updated to take account of risks from flammable liquids and other chemical risks?		
24.	Employees have received suitable training in emergency procedures?		

	Health and Safety	Y/N	Comments
25.	Appropriate risk assessments have been reviewed and updated including: <ul style="list-style-type: none"> • Fire risk assessments? • DSEAR risk assessments? • General risk assessments including for maintenance tasks? • CoSHH assessments? • Manual handling assessments? • Workplace transport assessments? 		
26.	Suitable measures are in place to prevent exposure of employees to substances hazardous to health?		
27.	Manual handling of drums/kegs has been avoided so far as is reasonably practicable?		
28.	Deliveries of raw materials, collections of product and vehicle movements around the site are being managed to reduce risk of pedestrian/vehicle impacts so far as is reasonably practicable?		
29.	Employees are provided with appropriate Personal Protective Equipment including safety footwear?		
30.	Safe working procedures are in place for maintenance tasks including breaking pipe work connections and working around areas where there may be a flammable atmosphere?		

LOSS PREVENTION STANDARDS

	Safeguarding Users of the Products	Y/N	Comments
31.	Formulations of products are approved by the WHO or have been subject to rigorous product safety testing by an accredited laboratory?		
32.	Product use has been determined and the product classified as either a cosmetic product, biocidal product or medicine?		
33.	Raw materials used are pharmacopeial grade and come with certificates of analysis?		
34.	There are means to demonstrate that water used in the products is sterile at the point of use?		
35.	There are means to ensure that bottles are sterile at the point of filling?		
36.	There are suitable methods deployed to analyse and determine both alcohol content and hydrogen peroxide content of each batch made?		
37.	Product labelling complies with the relevant regulatory requirements?		

	Notification of Interested Parties	Y/N	Comments
38.	You have necessary planning consents for this change of use including the storage of flammable liquids on site?		
39.	Any necessary permissions have been granted in respect of alcohol licensing including tax/duty implications agreed with HM Revenue & Customs?		
40.	Relevant regulatory bodies have been contacted in respect of product classification?		
41.	You have notified/discussed your proposals with your insurance broker and existing insurer?		
42.	If flammable liquids are a new hazard at the site, you have discussed or notified this to the Fire Brigade?		

LOSS PREVENTION STANDARDS

43.	Additional comments:
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LOSS PREVENTION STANDARDS