Distilled Spirits Aotearoa (NZ) Incorporated
New Zealand Business Number (NZBN): 9429047031708
Certificate of Incorporation: 2716891
Registered office 14 - 16 Harbour Street, Oamaru 9400, New Zealand
Telephone: +64(0)21 222 9881 email: chair@distilledspiritsaotearoa.org.nz
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DISTILLED SPIRITS AOTEAROA (NZ) INCORPORATED

Hand Sanitiser – Frequently Asked Questions

Coronavirus Pandemic - shortage of sanitisers is an ongoing global issue. The manufacture of hand sanitisers is an important initiative from distilleries to utilise unused 80% alcohol (eg. production heads and tails) and other unused alcohol sources. As local distillers, we have the ability to mobilise their alcohol handling expertise and facilities to assist our communities.

Working Group:
Brent Robinson (batch10) - Chair
Sue James (DSA) and Dave James (Juno Gin)
Ben Leggett (Elemental Distillery Co)
Antony Michalik (Spirits Workshop)
Soren Crabb (1919 Distilling Ltd)
Diana and Will Miller (Ecology+Co)
Rachael Thomson (Thomson Whisky)
Janet Charteris (LWF Distilling)
Joerg Henkenhaf and Gussie McDonnald (Broken Heart Spirits)
Blair Nicholl and Cristian Hossack (National Distillery Company Ltd)

Frequently Asked Questions:

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The information in this FAQ should be used as advice only. It is the Distillers own responsibility to cover aspects of the law and liability in their independent business decisions.

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(1) Legislation/Regulations and approvals required

While some of the legislational advice below may change after the COVID-19 event has finished, the **HSNO requirements** as listed in the Cosmetic Products group standard are on-going requirements for any hazardous substance assigned to this group standard.

(a) Restrictions on use

Current standard guidance from New Zealand Ministry of Health/Medsafe:

If the Hand sanitiser is for the public only:

Hand sanitisers for use by the public only, should be made according to specifications and requirements issued by a reputable regulator, such as the USA FDA (see the link in recipes below). Covid-19 protection should not be explicitly claimed. It is important to note that the product must be manufactured in a way that ensures it has the correct formulation, that it is safe and effective, labelled correctly and that it is fit for purpose. The supplier will be responsible for the quality of the product and needs to ensure compliance with the Fair Trading Act 1986, the Consumer Guarantees Act 1993 and the Cosmetic Products Group Standard 2017 (HSR002552) published by the Environmental Protection Agency (EPA). This advice applies only during the COVID-19 situation.

If the Hand sanitiser is for use in a health-care facility or by health care personnel:

Hand sanitisers or products used as antiseptics for skin application, that are for use in health care facilities or by health care personnel (whether or not they are also for use by the public) are medicines under the Medicines Act 1981 and should first be approved under the process that is operated by Medsafe. This "process" means manufactured by an approved pharmaceutical company under strict Pharmaceutical Level conditions, ie. Not a distillery. More information on product approval can be found on the Medsafe website (see: https://medsafe.govt.nz/Medicines/regulatory-approval-process.asp). If you wish to discuss a product further, or discuss a product supply issue please contact: medsafeapplications@health.govt.nz. This advice applies only during the COVID-19 situation.

If the Hand sanitiser is made using the WHO 80% formulation (see Recipes below):

From 2/4/20 Medsafe has "no objection" for the supply of the WHO 80% formulation to community pharmacies and other community-based health care facilities and personnel, if there is no medical sanitiser supply available. **Supply cannot be made to higher risk facilities, DHBs and hospitals.**

Current standard guidance from PHARMAC:

(Non medicine) Hand sanitiser does not fall under their HML Classification (section of medical pharmaceutical schedule) which lists the medicines which hospitals and DHBs can acquire through government funding. As such it is a privately funded good which individual DHBs and hospitals can manage with their own budgets and spending. It is up to each hospital (and even ward sometimes) to decide on their own (non medical) hand sanitiser product and supplier.

We advise our DSA members that if they have any doubts about who to supply to, they should send the following advice to the person ordering, and they can confirm to the distiller they are allowed to buy the product.

2 April 2020 - Medsafe has the following advice.

Advice to manufacturers / suppliers

Medsafe has no objection to the provision of hand (and skin) sanitiser that has not been approved as a medicine, to primary health care facilities and personnel provided there is no stock available of product that has been approved as a medicine. This does not apply to health care facilities where the risk is higher, such as DHB facilities and hospitals or for higher risk uses. Enquiries from DHBs and hospitals should be sent to PHARMAC, where nationwide demand for these products is being collated.

Those facilities or personnel requesting supply should have ensured that no alternative stock that is approved as a medicine is available to them. It will be for the purchaser / user and supplier / manufacturer to ensure that the product is fit for purpose and has been manufactured in an acceptable way. Manufacture according to a formula published by a reputable regulator such as the USFDA, the TGA (Therapeutic Goods Administration - Australia; see: https://www.tga.gov.au/hand-sanitisers-and-covid-19#_blank) or a European health care products regulator is likely to provide assurance that the formulation is acceptable. This advice is in recognition of the current difficult supply conditions and only applies during the COVID-19 situation.

Advice to users / purchasers

Community pharmacies and other community-based health care facilities and personnel should use hand (and skin) sanitisers that are approved as medicines. Under the present COVID-19 circumstances, in situations where these products are not available, Medsafe has no objection to the use of a product that is not an approved medicine, however, the product should be made to a formula that has been provided by a reputable regulator such as the USFDA, the TGA (Therapeutic Goods Administration - Australia; see: https://www.tga.gov.au/hand-sanitisers-and-covid-19#_blank) or a European health care products authority; and it will be for the pharmacy or community health care facility and the manufacturer / supplier to ensure that the product is fit for the intended purpose. This advice is in recognition of the current difficult supply conditions and only applies during the COVID-19 situation.

Currently, approved alcohol-based hand sanitisers include:

- Microshield Angel Clear hand gel, ethanol 70%
- Avagard Antiseptic Hand Rub ethanol 61%
- Cutan Alcohol Foam Antiseptic Hand Rub , ethanol 70%, IPA 11%
- Microshield Antiseptic Hand Rub Solution ethanol 10%, IPA 70%

References:

Derek Fitzgerald - Manager, Compliance Management, Medsafe, Ministry of Health, (04) 819 6866.
Matthew Spencer, Team Leader, Product Safety, Compliance Management, Medsafe, Ministry of Health (04) 819 6840

(b) Registration with EPA:

The EPA have published a fact sheet on their website outlining HSNO and other requirements for manufacturers and importers of hand sanitisers (make-sure-your-hand-sanitising-product-is-legal-in-new-zealand/).

Based on conversations with EPA: 80% Alcohol hand sanitiser is a hazardous substance. As a manufacturer of a hazardous substance, you are required to register with the Environmental Protection Authority. Here is the link to do so.

The full WHO 80% recipe complies with the Cosmetic Product Group Standard HSR002552. Cosmetic Products Group Standard 2017 - HSR002552 GROUP STANDARD and its associated schedules Cosmetic-Products-Group-Standard-Schedules-4-8. This means that food grade ethanol does not need to be separately denatured before it is used as an ingredient (see below in Recipes for information on denaturing).

References:

Kareema Yousif - Senior Advisor, Hazardous Substances Compliance. +64 4 474 5567.
Enda Costello - Senior Advisor, Hazardous Substances Compliance, +64 4 474 5502

(c) Safety Data Sheets

Since Hand Sanitisers are classified as a cosmetic good, not a food good, we are all required to have Material Safety Data Sheets of the final recipe and all of its constituent parts. SDS are highly detailed documents that cover traceability of hazardous or non-food grade cosmetic products. All distilleries should be well versed in SDS's as we have to retain records of any ethanol purchased or manufactured. Hand sanitisers fall under the conditions of the Cosmetics Products Group Standard 2017 approval HSR002552. The SDS template needs to meet HSNO requirements for SDSs as listed in the Hazardous Substances (Safety Data Sheets) Notice 2017 EPA NOTICE.

The only ingredient in the WHO recipe (see Recipe section below) that requires HSNO certification is the alcohol, and distilleries already conform to this Group Standard. Note that if a customer asks for an SDS, by law the supplier is required to supply this at that time, especially if there is a health or safety issue.

The DSA Working Group has created a template SDS for the WHO final recipe for all distilleries to use, and can provide an SDS for the ingredient ethanol if needed. This will be distributed with the FAQ.

References:

This link on the EPA website provides further guidance for manufacturers, including about SDS and labelling of hazardous substances.

Anyone with the Poison Centre details on their label will need to submit their SDS to the National Poisons Centre. We are unable to submit one single template SDS on behalf of all DSA. The Poisons Centre needs each individual manufacturer and brand name linked to the submitted SDS.

The NPC is happy to act as an emergency contact for first-aid or medical advice in the event of an acute exposure. The NPC number can be used on the product label or on the SDS or both. Our 24 hour contact within NZ is 0800 764 766 (0800 POISON). This service is currently free of charge.

If our number is used on the SDS or the product label, it is a legislative requirement that manufacturers or suppliers of chemical products provide us with a copy of the SDS. We then have the information readily available in case it is required in any poisoning situation. These should be supplied before a product is marketed.

Please note that under current legislation you must ask for the NPCs permission to put the NPCs number on an SDS or label. Digital pdf and word formats can be sent to the following email address: poisons@otago.ac.nz

Please note that .zip files are currently not accepted. Files must be named as per the products name on the label.

(d) Customs permit application form:

Excise duty is not payable on hand sanitiser, as the product does not fall within Part A of the Excise and Excise-equivalent Duties Table. The New Zealand Customs Service VOC office (Value Origin and Classification) are of the opinion that hand sanitiser would be classified under tariff item 3808.94.39L.

14/4/20 update from customs:
Most operators with DF permits for the manufacture of sanitiser have been informed by their customs agents that customs have decided to waver permit requirements during the COVID-19 situation to make it easier for manufacturers to source ethanol and produce sanitiser as required.

The email below from customs goes further in stating they are also now happy for distillers to use the specific volumes of ethanol (previously allocated through permit for sanitiser) for either distilled spirits or sanitiser now without any need for notification or permit updates.

> *Licensed Manufacturing Area's no longer need a permit to receive and use alcohol to distil and then make HS from the ethanol. You can buy it duty free as an LMA "for further manufacture", then keep manufacturing records, sale/usage records of the HS, which is auditable. You don't need a permit, and therefore you can use the ethanol for either purpose – you just need to keep the full manufacturing and distribution records for audit purposes.*

Naturally we need to be even more strict about what volumes go where and therefore what is excise payable vs not – but this frees us all up to choose our own production from any one source of ethanol.

Customs also provide this information:

> 4.5 Ethyl alcohol use for approved purposes
>
> Ethyl alcohol manufactured within your CCA may be used at a duty free rate for commercial or industrial application, except the manufacture of potable beverages, for example ethyl alcohol for use in laboratory tests and processes, cleaning, sterilising equipment, manufacture of hand sanitiser.
> The alcohol must be stored, handled, packaged, and transported in accordance with WorkSafe New Zealand, Ministry of Business, Innovation and Employment, and Environmental Protection Authority requirements.
> You must keep records detailing the quantity, strength, date used, purpose, and loss of any alcohol. You must keep records for a period of at least 7 years, and provide Customs with access to such records for audit purposes.
> Any waste or residual ethyl alcohol from this approved use is not to be rectified, reworked or reconstituted to produce ethyl alcohol unless approved by Customs.
> The ethyl alcohol, including any waste from the approved use, is not to be on-sold or otherwise disposed of except in a manner approved by Customs.
> The ethyl alcohol you have manufactured may be supplied to other manufacturers licensed by Customs but must not be supplied to other persons unless they hold a valid Permit to receive and on-supply or a Permit to receive and use. If you require more information on this process, please contact your local excise officer.
> If you use the ethyl alcohol for any other reason than that which it is approved for, or you cannot satisfy Customs in regard to any discrepancies that are identified, then you may be charged the excise duty that would otherwise be payable.

You must ensure that all staff that are involved in the storage, handling, and use of the ethyl alcohol are familiar with the requirements of this approval.
You must also advise Customs in writing of any intended changes for this approval.

(e) Hazardous Substances

Glycerol and H2O2 are Hazardous Substances. They need to be added to your Hazardous Goods register and SDS must be kept. Glycerol is Toxic 6.8B but there is no designated Tolerable Exposure Limit specified Approved hazardous substances with controls.

Most distillers are using H2O2 at a concentration of 35% or less. While this is still corrosive, it is still Food Grade and obtainable without the need of a permit or further qualification. All hydrogen peroxide in its supplied concentrations and diluted should be properly labelled and contained. Wear PPE when handling and ensure staff are trained. Hydrogen peroxide is a strong oxidising agent and must be stored separately from other chemicals. Strong oxidising agents can initiate or accelerate the combustion of other materials. This can lead to more dangerous fires and potentially explosions.

The Cosmetics Products Group Standard 2017 approval HSR002552, and its associated schedules Cosmetic-Products-Group-Standard-Schedules-4-8 has regulations about the amount of hazardous substances that are allowed in cosmetics. The maximum authorised concentration of methanol allowed as a denaturant for ethanol in the finished cosmetic product is 5% calculated as a % ethanol. The maximum amount of hydrogen peroxide allowed in skin-care preparations is 4% of H2O2, (present or released). If the WHO recipe is followed, these chemicals fall under these limits.

(f) Restriction in volumes produced in one batch/ volumes that can be couriered

80% Ethanol is categorised as class 3.1B under New Zealand HSNO regulations – Flammable Liquid with a Flashpoint <23 degrees and a Boiling Point > 35 degrees. The addition of the small amounts of Glycerol and H2O2 would not likely change the flammability enough to change the classification from that of just an 80% Ethanol and Water dilution or add any new classification, therefore hand sanitiser is also classed as 3.1B.

Hand Sanitiser - since it is not intended for drinking - does not qualify for the clause 1.9 exemption for any volume storage of packages <5L, therefore the storage of packaged Hand Sanitiser is restricted by the regulations. Neither does the clause 8.7 ethanol dilutions exclusions apply and therefore clauses 8.1, 8.3 and Part 10 of the regulations do apply to Hand Sanitiser, where they do not apply to ethanol dilutions intended for drinking (that meet the other criteria of clause 8.7).

8.1 is the requirement for your Location Compliance Certificate to be renewed every 12 months.
8.3 is the regulation that specifies how much of a hazardous substance you can carry on ordinary transportation. For 3.1B this is specified in Schedule 6 of the regulations. **The maximum package size able to be transported in a "passenger service vehicle" is 1L. This means that any quantity >1L Hand Sanitiser must be transported by a DG certified carrier.**
Part 10 is the part that requires a Location Compliance Certificate (including designated hazardous areas, hazardous locations and notifications, emergency response plan), if you are using more than 50L in open containers, or storing >250L in closed containers of <5L, or >100L in closed containers of >5L, of a class 3.1B substance.

Summary:

- **If you do not have a current Location Compliance Certificate at your distillery (i.e you are operating under the clause 8.7 exclusions), then you are limited to making <50L batch sizes and storing <100L in containers >5L or 250L in containers <5L.**

- **If your distillery has a current Location Compliance Certificate then you can operate up to whatever volumes you are currently certified.**
- **You can only transport up to 1L in your car, larger volumes must be transported as DG.**
- All the other requirements of the regulations, labelling, PPE, training etc of course still also apply.

(g) Transport by NZ Post

All effective hand sanitisers have an alcohol content of over 60% and this would make them a class 3.1 dangerous good for transport. NZ Post can carry these but an approvals process is needed for safe transport:

> Complete the form Application for Exemption from NZP Dangerous Goods Policy, and send to your Courier Post/ NZ post contact (CourierPost Enquiries: 0800 268 743, NZ Post Enquiries: 0800 501 501) with the product SDS sheet. Approval generally takes around 24 hours.

Talk to your local Courier Post Account Manager about discounts: As a dangerous good there is a great deal more handling required by NZ Post that would normally attract a premium of $7.86 a parcel. To support initiatives such as distilleries producing hand sanitiser, NZ Post has reduced this cost to $5 and this would stay in place until Covid 19 threat lifts above Level 3.

(h) Requirements when sending a Dangerous Goods parcel:

For DG shipping domestically the regulations for on-road transportation of DG products is governed by the safe guidelines for maritime shipping. Only airfreight falls under different guidelines. For on-road transportation there is a limit of no more than 50L allowed to be shipped in any single consignment. If using Courier there will be the usual 20kg (20L) maximum per package for safe carrying.

Transportation of 3.1B falls into one of three UN Packing Groups;

(1) UN1170 Packing Group III - Small bottles (30ml):

Classified as “Excepted Quantities” and do not require standard DG paperwork.

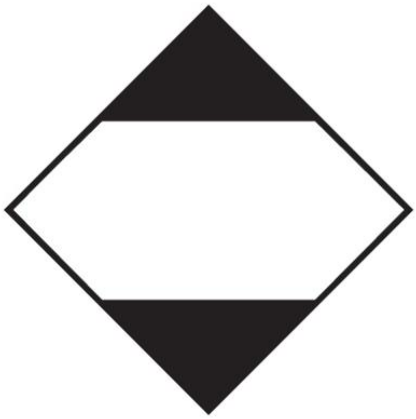
(2) UN1170 Packing Group II - Larger bottles (<1L):

Classified as "Limited Quantities” and qualify for any boxes with bottles of 1L or less in them (you could have 10x 500ml bottles or 20x 1L bottles in a box).

- The requirement is DG Paperwork and the DGLQ (Dangerous Goods in Limited Quantities) label below
- In the cases where a fibreboard box is used you should list the number and size of the bottles in the box on the DG paperwork. Note: wrapping postal paper/card is also acceptable as a 'fibreboard box'.

You will need:

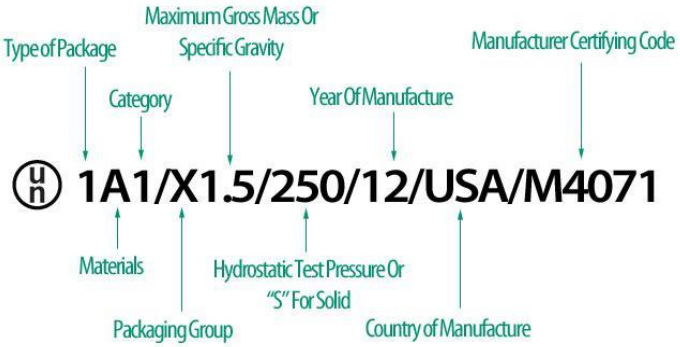
1. CourierPost DG ticket (with the Gross weight of the item, the consignee address, sign and dating of the paperwork)
2. 2 x copies of the DG declaration specific to every parcel (1 in a pouch on the item and 1 for the Courier/Truck driver).
3. DG Diamond for the class - **A Limited Quantity DG label** is needed on the outside of the box (see here).
4. No additional statements are required on the packaging



(3) UN1170 Packing Group I - Larger bottles / containers (>1L):

For sanitiser packages exceeding 1L in volume. Multiple containers over 1L per package are allowed.

You can pack and send Class 3.1B dangerous goods in containers larger than 1L but they MUST be UNSPEC packaging – showing the UN Mark (UN Markings Guide - How to Read and Identify UN Packaging Codes). If UNSPEC bottles/plastic Jerrycans are placed in a cardboard (fibreboard) box that box MUST also be UNSPEC rated - showing the UN Mark on the outside of the carton. (see section on Packaging).



You can send a single UNSPEC jerry can filled with (3.1B) sanitiser over 1L, without any additional box or packaging around it as long as the appropriate paperwork and pictograms fit on the outside of the container. The Jerrycan requires the correct UNSPEC plastic jerrycan DG paperwork. This is the shipping template which is supplied by the DG transport company upon registering yourself as a DG shipper in the first place.

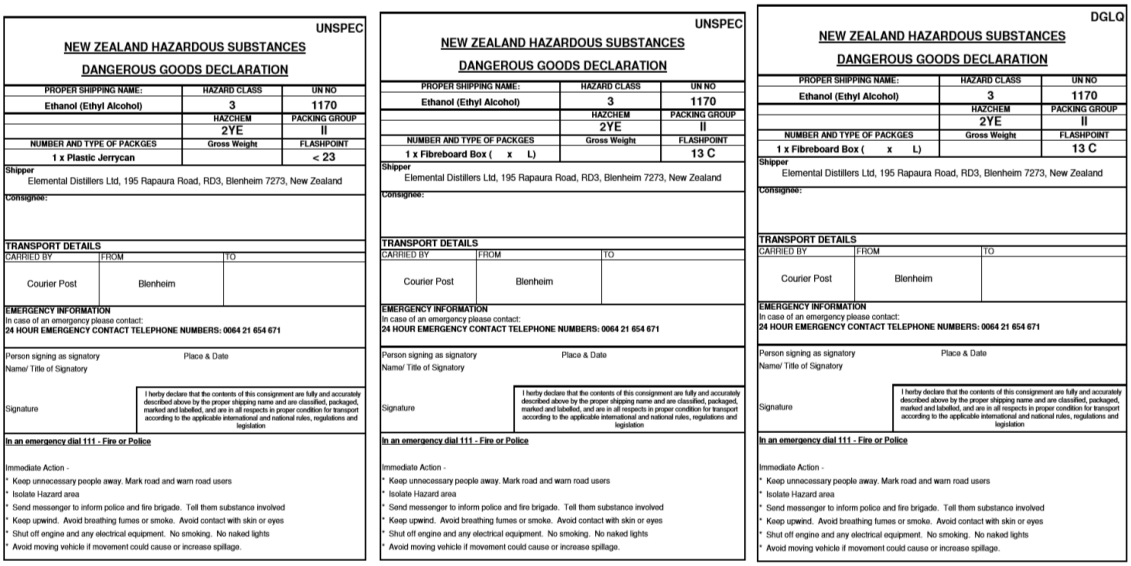
You will need:

1. CourierPost DG ticket (with the Gross weight of the item, the consignee address, sign and dating of the paperwork)
2. 2 x copies of the DG declaration specific to every parcel (1 in a pouch on the item and 1 for the Courier/Truck driver).
3. DG Diamond for the class - **Class 3 Flammable Liquids label** (see here) is needed on the outside of the box.
4. "UN1170 Ethanol (Ethyl Alcohol)" is required either printed on your company's label or on a small independent label on the package.

(NB: All these labels can be ordered from DGM (dgm.co.nz) or Officemax or Blackwoods – please compare the prices before ordering)

Examples of DG declaration Paperwork for the class

- UNSPEC PJ - This is for 20L Plastic Jerrycans (not in a box)
- UNSPEC FB - This is for any bottles over 1L in a Fibreboard box
- DGLQ FB - This is for any bottles of 1L or less in a Fibreboard box



UNSPEC

NEW ZEALAND HAZARDOUS SUBSTANCES

DANGEROUS GOODS DECLARATION

PROPER SHIPPING NAME:	HAZARD CLASS	UN NO
Ethanol (Ethyl Alcohol)	3	1170
	HAZCHEM	PACKING GROUP
	2YE	II
NUMBER AND TYPE OF PACKGES	Gross Weight	FLASHPOINT
1 x Plastic Jerrycan		< 23

Shipper
Elemental Distillers Ltd, 195 Rapaura Road, RD3, Blenheim 7273, New Zealand

Consignee:

TRANSPORT DETAILS

CARRIED BY	FROM	TO
Courier Post	Blenheim	

EMERGENCY INFORMATION
In case of an emergency please contact:
24 HOUR EMERGENCY CONTACT TELEPHONE NUMBERS: 0064 21 654 671

Person signing as signatory | Place & Date
Name/ Title of Signatory
Signature

I herby declare that the contents of this consignment are fully and accurately described above by the proper shipping name and are classified, packaged, marked and labelled, and are in all respects in proper condition for transport according to the applicable international and national rules, regulations and legislation

In an emergency dial 111 - Fire or Police

Immediate Action -
* Keep unnecessary people away. Mark road and warn road users
* Isolate Hazard area
* Send messenger to inform police and fire brigade. Tell them substance involved
* Keep upwind. Avoid breathing fumes or smoke. Avoid contact with skin or eyes
* Shut off engine and any electrical equipment. No smoking. No naked lights
* Avoid moving vehicle if movement could cause or increase spillage.

UNSPEC

NEW ZEALAND HAZARDOUS SUBSTANCES

DANGEROUS GOODS DECLARATION

PROPER SHIPPING NAME:	HAZARD CLASS	UN NO
Ethanol (Ethyl Alcohol)	3	1170
	HAZCHEM	PACKING GROUP
	2YE	II
NUMBER AND TYPE OF PACKGES	Gross Weight	FLASHPOINT
1 x Fibreboard Box (x L)		13 C

Shipper
Elemental Distillers Ltd, 195 Rapaura Road, RD3, Blenheim 7273, New Zealand

Consignee:

TRANSPORT DETAILS

CARRIED BY	FROM	TO
Courier Post	Blenheim	

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In case of an emergency please contact:
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* Shut off engine and any electrical equipment. No smoking. No naked lights
* Avoid moving vehicle if movement could cause or increase spillage.

DGLQ

NEW ZEALAND HAZARDOUS SUBSTANCES

DANGEROUS GOODS DECLARATION

PROPER SHIPPING NAME:	HAZARD CLASS	UN NO
Ethanol (Ethyl Alcohol)	3	1170
	HAZCHEM	PACKING GROUP
	2YE	II
NUMBER AND TYPE OF PACKGES	Gross Weight	FLASHPOINT
1 x Fibreboard Box (x L)		13 C

Shipper
Elemental Distillers Ltd, 195 Rapaura Road, RD3, Blenheim 7273, New Zealand

Consignee:

TRANSPORT DETAILS

CARRIED BY	FROM	TO
Courier Post	Blenheim	

EMERGENCY INFORMATION
In case of an emergency please contact:
24 HOUR EMERGENCY CONTACT TELEPHONE NUMBERS: 0064 21 654 671

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* Keep upwind. Avoid breathing fumes or smoke. Avoid contact with skin or eyes
* Shut off engine and any electrical equipment. No smoking. No naked lights
* Avoid moving vehicle if movement could cause or increase spillage.

References:

DG Contact for any shipping questions: Mike Perkins, Dangerous Goods Specialist, Dangerous Goods Management Ltd, 18 Syd Bradley Road, Christchurch, MOB +64 27 577 2213

(2) Approved Recipe

After thorough research, DSA strongly recommends only using the WHO recipe below. Much of the rest of the information in this FAQ is based on the classification of this recipe as a cosmetic with its related HSNO and DG ratings. Other hand sanitiser recipes will need to be assessed differently.

The NZ Ministry of Health states that hand sanitisers should be made according to specifications and requirements issued by a reputable regulator, such as the USA FDA. The FDA uses the same recipe and volume strengths as described in the "WHO recommended handrub formulation".

References:
(1) WHO Guide to Local Production: WHO-recommended Handrub Formulations
(2) FDA Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19)

WHO Recipe

Per 10L
Ethanol 96%: 8333 ml
Hydrogen peroxide 3%: 417 ml
Glycerol 98%: 145 ml
Topped up to 10L mark with sterile distilled or cold boiled water

This makes a final product of:

Ethanol 80% (v/v)
Hydrogen peroxide 0.125% (v/v)
Glycerol 1.45% (v/v)

The WHO recipe doesn't detail whether the ingredients used to make the sanitiser are w/w or v/v to start with. We are assuming it is v/v, because the final product is v/v. **If your ingredients are supplied in w/w, then you will need to adjust the amount of ingredients used based on this - it makes quite a difference**. For example, if you have been supplied with 35% **w/w** Hydrogen Peroxide: Hamilton Chemicals have advised that the easiest way to calculate the change is: 1L of 35% **w/w** Hydrogen Peroxide to 8L of water will produce 9L of 3% **v/v** Hydrogen Peroxide. Mix this up first then use standard WHO ratios.

Place the bottles in quarantine for 72 hours before use. This allows time for any spores present in the alcohol or the new/ reused bottles to be destroyed.

Only pharmacopoeial quality raw ingredients should be used (e.g. The International Pharmacopoeia) and not technical grade ingredients. The addition of fragrances is not recommended because of the risk of allergic reactions.

Normal quality control testing should be followed (see WHO document), and records kept, as part of your Good Manufacturing Practices, National Program 3/ NZ Food Safety. Be very careful about producing in a sterile environment - you will need paperwork for each batch, the manufacturing processes and steps to ensure there is no contamination. This should be much more rigorous than

distilling, since you are becoming “medicine/cosmetic” manufacturers. Make sure that you keep test bottles of each batch that you make, to ensure that you can test the product afterwards if there is a complaint.

Active ingredients:The alcohol performs the sanitisation while the glycerol acts as a gelling humectant agent to mildly moisturise and lessen the drying of skin from the alcohol contact. The H2O2 “helps eliminate contaminating spores in the bulk solutions and recipients and is not an active substance for hand antisepsis”. See the link to a good video which explains how sanitisers work: Do hand sanitizers really kill 99.99 percent of germs?

The consistency is very liquid, and works well in all forms of dispenser, spray or pour, and dries quickly.

WHO/FDA state that it is important that no other active or inactive ingredients are added. Different or additional ingredients may impact the quality and potency of the product. Do not add any other active or inactive ingredients, including gelling agents, colours, fragrances or emollients.

Alcohol strength

There are many studies about the best concentration of alcohol that is effective in hand sanitisers. Concentrations as low as 60% have been discussed, however it is known that some additives negatively impact upon the effectiveness of the material eg. glycerol.
For consistency, known effectiveness, and the ability to label that WHO recommendations are followed, with the benefits covered above, **DSA recommends that distillers follow the FDA/WHO recipe above (80% alc) exactly.**

Denatured Alcohol

While the WHO recipe does not specify that the alcohol used should be denatured, the FDA recommendation restates the recipe in its own document, and in this version it does include denaturing:
*The hand sanitizer is compounded using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:5 a. Alcohol (ethanol) (80%, volume/volume (v/v)) in an aqueous solution **denatured** according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20; or Isopropyl Alcohol (75%, v/v) in an aqueous solution.6 b. Glycerol (1.45% v/v).7 c. Hydrogen peroxide (0.125% v/v). d. Sterile distilled water or boiled cold water.*

As long as you mix something toxic into food grade alcohol, it becomes denatured. ‘” Denaturing alcohol does not chemically alter the ethanol molecule unlike the denaturation process in biochemistry. Rather, the ethanol is mixed with other chemicals to form a foul-tasting, often toxic, solution. For many of these solutions it is intentionally difficult to separate the components”.
In USA there is a large list of chemicals that can be used to denature alcohol, including Glycerin (Glycerol), U.S.P, therefore - if the WHO recipe is followed, the alcohol is denatured.

References:
The USA method for denatured alcohol https://www.govregs.com/regulations/title27_chapterI_part21
List of denaturing chemicals: 27 CFR 21.151 - List of denaturants authorized for denatured spirits.

Use of SAA (Sanitiser Anhydrous Alcohol) as an alcohol source

Recently SAA (Sanitiser Anhydrous Alcohol) 99.7% has become available to companies making hand sanitisers. It has been imported from Australia through Gull by Lactanol and is manufactured from sugar cane, denatured and explicitly produced for sanitisation.

They have three grades of standard denaturant available – Methanol (F3), TBA (F4) or Bitrex(F6). Info on F4 & F6 can be found below;

> TBA (tert-Butyl alcohol) - a soft toxin with a strong odour - https://en.wikipedia.org/wiki/Tert-Butyl_alcohol
>
> Bitrex (Denatonium) Bixtrex is the most bitter agent in existence - https://en.wikipedia.org/wiki/Denatonium

Lactanol has stated that SAA has been tested by an independent laboratory and approved by Lactanol's Health and Safety team as suitable for use in hand sanitiser formulations. A specification, SDS and Lactanol statement is available.

The Working Group believes there is no issue using SAA as the source of your ethanol in the WHO recipe. We recommend selecting the methanol denatured product since this is allowed by FDA. In New Zealand the maximum authorised concentration of methanol allowed as a denaturant for ethanol and isopropyl alcohol in the finished cosmetic product is 5% calculated as a % ethanol and isopropyl alcohol (as listed in the EPA schedules Cosmetic-Products-Group-Standard-Schedules-4-8 *Components Cosmetic Products Must Not Contain).* SAA fits within this regulation.

(3) What should be on a label

Hand Sanitisers in New Zealand qualify as a "Cosmetic" so we need to follow the guides in Cosmetic Products Group Standard 2017 - HSR002552 GROUP STANDARD .
The labelling information on hydrogen peroxide below aligns with the HSNO requirements for labelling as listed in Hazardous Substances (Labelling) Notice 2017 EPA NOTICE.

The WHO recipe and FDA documents also contain guidelines for labelling. If we combine the mandated information we get:

Name: Alcohol Antiseptic 80% Topical Solution Hand Sanitizer

- **Non-sterile Solution**
- For external use only
- Do not use on open skin wounds
- Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Centre right away.
- Use: Apply a palmful of alcohol-based handrub and cover all surfaces of the hands. Rub hands until dry
- Composition: ethanol *or isopropanol*, glycerol and hydrogen peroxide
- Contains hydrogen peroxide. Avoid contact with eyes. Rinse immediately if product comes into contact with them
- Flammable: keep away from flame and heat
- Store between 15-30oC (it is not advised to store this product in your car)
- *Contact address of distillery*
- Date of production and batch number

We could also add:
Following approved WHO recipe and FDA recommendations
And maybe *Supported by Distilled Spirits Aotearoa (NZ) Inc (***You must be using the WHO recipe exactly, without additives, to be endorsed on the DSA website).**

There appears to be a NZ-wide lack of the pump dispenser parts, therefore people should be encouraged not to throw these away, and reuse them in the new bottle. If reuse of containers/ parts is the case this message should be shared: *Keep this product in the container supplied or transfer the provided label onto the new container.* Reusable bottles should never be refilled until they have been completely emptied and then cleansed and disinfected (see further information in Packaging below).

Claiming "Kills Germs":
It is generally reported that the FDA's rule is that makers of over-the-counter antiseptic products may claim only that they "help reduce bacteria that potentially can cause disease." They may not claim a product "kills microorganisms." FDA: Hand Sanitizers Make False Claims. In New Zealand the Medicines Regulations 1984 Act allows hand sanitisers to have a general claim about the prevention of the spread of bacteria. However, this general claim must be able to be substantiated and it does not extend to any named virus such as COVID-19.
If you make a claim that your product "kills 99.9% of germs", you may at some point be required to show you have proven this by lab testing (also see below - claims in advertising).

Advertising

There are laws around what you can claim/say about cosmetics and medicines in your advertising/promotion (which would include social media). Distillers largely do their own advertising/social media so we should be aware not to make certain claims when marketing any new hand sanitiser products. The NZ Advertising Standards Authority reminds advertisers that prior to preparing and placing their advertisements, they are expected to;

- Be familiar with the relevant legislation and codes; and
- Observe a high standard of social responsibility; and
- Ensure their advertisements are truthful and they must not be misleading; and
- Ensure their advertisements do not confuse consumers, abuse their trust, exploit their lack of knowledge or, without justifiable reason, play on fear; and
- Ensure their advertisements do not exaggerate or raise unrealistic expectations or outcomes.

Important points to remember when advertising therapeutic and health products or services include:

- COVID-19 has not resulted in any changes to the legislation or codes that advertisers of therapeutic and health products or services are expected to adhere to.
- The legislation and codes apply to both actual and implied claims in advertisements.
- Only products and services specified in the Medicines Act 1981 are able to make therapeutic purpose claims in advertisements, including any therapeutic purpose claims to test, diagnose, prevent, treat or cure COVID-19. Any therapeutic purpose claims must be able to be substantiated by the advertiser.
- Other products and services may make health benefit claims in advertisements only if such claims can be substantiated by the advertiser. Health benefit claims should not refer to COVID-19 or imply a reference to COVID-19.
- **Claims for hand sanitiser products that refer to COVID-19 or imply a reference to COVID-19 must be able to be substantiated by the advertiser.**

Hand Sanitisers:

- These products are not ‘consumed’ for internal purposes so they do not strictly fit the definition of a therapeutic or health product or service. They are applied on the surface of the skin.
- The ASA Codes do apply to advertisements for these products and of course, the Fair Trading Act also applies. Any claims specific to COVID-19 made in an advertisement about a hand sanitiser or similar product must be able to be substantiated with scientific proof.
- There is an exemption in the Medicines Regulations 1984 that allows a general claim to be made for the prevention of the spread of bacteria. This may be considered a ‘therapeutic purpose’ despite these products not being medicines or medical devices. It is important to note, that even this general claim must be able to be substantiated by the advertiser and it does not extend to any named virus such as COVID-19.

References: https://www.asa.co.nz/resources/covid-19-advertising-health-products/

AdHelp Information Service:

- Advertising Standards Authority (link ASA) provides a user-pays service for advertisers requiring information on relevant ASA codes and guidance note, legislation that may impact on your advertisement, industry codes or guidelines that may be applicable, precedent advertising standards complaints board and / or appeals board decisions that may be relevant to your query or issue.

DSA Publicity
We want to promote the work the DSA members are doing on the DSA Website (https://distilledspiritsaotearoa.org.nz/). If you are making the WHO recipe Hand Sanitiser and agree to have your Distillery name and Web address posted on the new Hand Sanitiser page then email Sue (sue@distilledspiritsaotearoa.org.nz). There will be a caveat in the wording that most distilleries already have long waiting lists.
You must be using the WHO recipe exactly, without additives, to be endorsed on the DSA website.

(4) Sourcing ethanol/alcohol - What are the existing supply chain channels for alcohol/ethanol in NZ, and what is the current availability.

Axieo
Wendy Lawson
sales.nz@axieo.com
ethanolsales@axieo.com
+64 (0)9 259 3772
Comment: Fonterra Ethanol: Axieo is our national distributor and we're putting virtually all volumes through them.
FYI – Lactanol, with the support of Axieo have supplied already ~1million litres of Ethanol into the sanitiser manufacturers and are currently supplying circa 300,000 litres per week, up from only 80,000/week a few weeks ago. This has been achieved through increasing the number of supply channels, especially wrt companies packing from bulk into drums and IBC – the only packaging that 90% of the manufacturers can legally use on their sights (volume of Dangerous goods restrictions). We've also been ensuring that our ethanol is going to a broad range of sanitiser manufactures so that supply reaches all essential services such as pharmacies, hospitals, rest homes and emergency services as well as retailers to service the general population.

Evolution Brands (EBL)
Brendan Durant
hello@spiritual.vodka
+64(0)212629966
Comment: Imported beverage grade ethanol (sugar). EBL is creating an indent order for containers of beverage (potable) 96.4% sugar ethanol (please see COA attached) due into NZ end May / early June for clients who are looking for stock. As this is a rather urgent procedure, it is based on a first come first serve basis as stock is limited to 280 drums with 80 of these pre-sold already since 22 March 2020.

Australia & New Zealand Distillery Ltd
PO Box 1959, Christchurch
Ph (03) 967 1888 Fax (03) 384 0335
http://www.anzdistillery.co.nz/
admin@anzdistillery.co.nz
Comment: Suppliers of foodgrade ethyl alcohol for use in manufacture of spirits, liqueurs, Pharmaceuticals, and deer velvet processing. Presume they are still operating.

(5) Sourcing packaging (bottles) - Providers, and associated product descriptions

In New Zealand the packaging for hand sanitiser with HSNO requirements needs to be in compliance with the Packaging-Notice-2017. Hand sanitisers using the WHO 80% alcohol recipe are classed as HSNO class 3.1B

- **The Hazardous Substances (Packaging) Notice 2017 states that the maximum quantity per unit of packaging is 1.0L for HSNO class 3.1B (see below for a >1L exception)**
- **Glass packaging is not acceptable.**

Packaging for a hazardous substance that is a dangerous good must be certified as meeting the requirements to contain the substance, in this case Subclass 3.1 Category B Substances that are flammable liquids/ Subclass 6.4 Category Substances that are irritating to ocular tissue. Discuss this with your bottle supplier, and obtain a certificate if necessary.

Packaging must be able to retain its contents

(1) When filled and closed, the packaging for a hazardous substance must-

(a) not leak any substance when subjected to the normal stresses and strains of handling; and

(b) maintain its ability to retain its contents in the range of environmental or temperature conditions to which it is likely the package may be subjected throughout its lifecycle;

(c) not release any gas or vapour unless the packaging is specifically designed to be vented; and

(d) maintain its ability to retain its contents if part of the contents are removed and the packaging is resealed.

(2) The packaging for a hazardous substance must not react with the hazardous substance to generate another hazardous substance, or to weaken the packaging in any way.

Performance tests

Packaging must be tested using the particular hazardous substance to be contained or another substance with similar physical characteristics including density, viscosity, and particle size. The closure mechanism of the package must be fully closed and, in the case of vented packaging, the vents must be sealed. The tests are:

(1) The package for the hazardous substance must be able to withstand the impact at any orientation of a drop of 0.5 m to a hard surface without losing its ability to retain its contents.

(2) In the case of a liquid substance, the package must be leakproof when the package is held with the opening at the lowest point for a period of 30 minutes.

Packages with hand sanitiser (a class 3.1B substance) of less than 0.1L do not need to pass the performance test, but need then to have a warning statement stating that the package may not withstand a drop of 0.5m. This wording needs to be easily read by a person with normal eyesight.

The packaging for HSNO class 3.1B does not need to be child-resistant. However, packaging for a hazardous substance that is supplied or intended for supply to the general public must not have a shape or a design (or both) that is likely to attract or arouse the active curiosity of children.

Packaging for a hazardous substance that is supplied or intended for supply to the general public must not have a presentation or a design (or both) that may mislead consumers as to the nature, characteristics, or suitability for a purpose of a hazardous substance (for example, that it contains human foodstuffs or medicinal products when it does not). Avoid too close a similarity to your spirits packaging.

For those distillers packaging large volumes meant to be “refills”, they need to be aware of compatibility when the hazardous substance is repackaged. When a hazardous substance is packaged in packaging that has previously contained another substance:

(a) both substances must be compatible (in the range of environmental or temperature conditions that the package is likely to be subjected to throughout its lifecycle; and substance A is not chemically reactive when brought into contact with substance B); or
(b) all practicable steps must be taken to remove all residues of the original substance.

Containers greater than 1L
You can pack and send Class 3.1B into containers larger than 1L but they MUST be UNSPEC packaging – showing the UN Mark (UN Markings Guide - How to Read and Identify UN Packaging Codes). UNSPEC packaging is tested to withstand a drop from specified heights. If UNSPEC bottles/plastic Jerrycans are placed in a cardboard (fibreboard) box that box MUST be UNSPEC also - showing the UN Mark on the outside of the carton. You can find out more about UNSPEC packaging at the following link. UN Approved Packages and Specification Marks. See the section on Requirements when sending a Dangerous Goods parcel above, for more information.
See below for a UNSPEC rated jerry can supplier.

Suppliers:

Dangerous Goods Management Ltd (DGM)
operations@dgm.co.nz
39 Richard Pearse Drive, Airport Oaks, Auckland, 2022
https://www.dgm.co.nz/shop/
Comment: Has UNSPEC rated jerry cans and cartons

EPI Plastics
225 Kaikorai Valley Road, PO Box 310, Dunedin
www.epiplastics.co.nz
Freephone 0800 448 548
office@epiplastics.co.nz

Futurity Group
Ella Gordon-Latty
sales@futuritygroup.co.nz
Mobile: 021 122 9377
futurity.co.nz
Comment: For background, we are not bottle manufacturers per say, we are a pre launch company who were planning to produce bottles for ourselves and our own product. We are a small team of 4, who will endeavour to serve you the best as possible- please bear with us if we don't know everything, we are working as fast as possible to rejig our supply chain and operations to serve this new and important purpose. Attached are the technical drawing of the bottle and the cap, as well as photos, which show the small F water mark on the top of the cap, as well as embossing on the base of the bottle- we can't change either of these due to our moulds, how ever we are looking into getting alternative caps, such as flip top, trigger sprays and pump- alternatively, if you have your own caps, we can look at discounting our prices.

Information on the bottles:
Production timeline: We are ready to produce as soon as orders are taken- we just need to turn the machine on, get it warmed up and start making bottles.
Production Capacity: 10,000 per day
Shipping: We use mainfreight and shipping time will be dependent on location, otherwise we can use your shipping partner if faster and easier
Location: We manufacture out of Wigram, Christchurch

Pricing: $1.00 NZD per 650ml bottle and 1881 PCO screw cap - discounts on the table below
Packing: Our bottles are packed into clear film bags, then put into cardboard boxes and sent-around 2000-3000 per bag, however this can be adjusted to suit how you want your order dispatched.
MOQ: We fulfill orders of 500 or more
Terms and conditions: To be provided prior to expressing definite interest in the product.

Pricing and Discounts

500-10,000	10,000- 20,000	20,000- 30,000	30,000-40,000	40,000- 50,000
$1.00	$0.95	$0.90	$0.85	$0.80

Product Details
Width is 7.49cm / Height is 21.06 cm/ Depth is 6.7cm
Bottle is made from Poly Lactic Acid (PLA) a sugarcane derived bio plastic and will act like plastic when put under heat or light
Bottle and cap are made from biodegradable material and are industrially compostable
Bottles can be reused
Comment from Rachael Thomson - *be aware this bottle appears to be tapered so wouldn't go on the bottling machine easily?*

Cospak
27 Ross Reid Place
EAST TAMAKI 2013
Auckland, New Zealand
Tel: +64 (0)9 253 9805
http://www.cospak.co.nz/
Email: sales@cospak.co.nz
Comment: They will come back Mon:Tue with short and long term availability of 100ml 500ml and 1000ml bottles with spray and refill closures. Sounds like they have good availability and are keen to do a bulk deal. Alison gets what we are trying to achieve.
Cospak definitely have the scale and capacity to bounce back quickly. They are also based out of Aus so should have good access to stores.

Comag Agencies
8D Piermark Drive,
Rosedale, Auckland
Mobile: 021 151 4363
https://www.comag.co.nz/
Comment: Terry at Comag Agencies has a wide range of plastic bottles and a variety of closures.

Arthur Holmes
Wellington
https://www.arthurholmes.co.nz/
Comment: has always been my favourite company to deal with but are fully stretched like so many.

Due to the extremely high volume of orders and limited stock levels, we have no option but to close down the website until further notice. We cannot guarantee that any orders placed after the 16th March 2020 will be processed at this point. We apologise for any inconvenience this will cause. OFFICE OPEN FOR ALERT4 ESSENTIAL ORDERS BY PHONE ONLY 0508 894103.

LWF Distilling
Janet Charteris
Comment: I'm using 10litre containers

(6) Sourcing labels - Providers, and associated product descriptions

Label & Litho Limited - Camilla Welch
151 Hutt Park Road, Gracefield 5010
PO Box 38-412, Wellington Mail Centre 5045
Phone: 04 568-3696 ext. 821
Mobile: 021 727-722
www.label.co.nz
Comment: here at L&L we can help with the printing of hand sanitizer labels. We are currently printing hundreds of thousands of them with great urgency

Narrative Brands - Jamie Turnbull
4 Richard Hill Close,
Fairview Heights, North Shore
Auckland
Mobile: 0277823572
jamie@narrativebrands.co.nz
Comment: Jamie has put together a template for some sanitiser labels which could be a quick option for any distilleries which don't have their own design resource available. An example will be sent out with the updated FAQ Version 4. Contact Jamie for more information

Adhesif Labels - Michael Schofield
19 Smales Road
East Tamaki
Auckland 2013
Mobile: 021922890
michael@adhesif.co.nz
Comment: Adhesif Labels will remain open as well.

Kale Print
Email: kale@kaleprint.co.nz, Stephenk@kaleprint.co.nz
219 Cameron Road
PO Box 13039
Tauranga 3141
Ph 07 578 7506
Comment: Kale Print can do stickers and turn around quickly.

Leading Labels
Shelley Tullet
107 Montreal Street, Christchurch
New Zealand, 8240
Phone: 0800 522 532
Mobile: 022 043 6026 or 027 222 0955
Email: sales@leadinglabel.co.nz shelley.tullett@leadinglabel.co.nz
Comment: Print pharmacy labels so are operating. Can offer a quick turnaround service for simple black and white labels.

(7) Sourcing chemicals - providers, and associated product descriptions

H2O2 - 50% solution in 20 litre
Ecochem Limited
217 Lichfield Street
Christchurch 8011
Telephone
03-377 1892
https://www.ecochem.co.nz/

Glycerol/Glycerine 99.9% - 5 litre and 24kg (~20 litre)
Zen Designs
22c Portside Drive
Mt Maunganui, 3116
PH: 07 578 4755
https://zendesigns.co.nz/
support@zendesigns.co.nz
Comment: Yes! We are still able to send out to essential businesses and their supply chains. Please email us directly at support@zendesigns.co.nz

Glycerol and H2O2
Hamilton Chemicals
Phone: (07) 974-4971
75 Ruffell Road, Te Rapa, Hamilton, NZ
Email: info@hamchem.nz
https://hamchem.co.nz/

Distilled Spirits Aotearoa (NZ) Incorporated
New Zealand Business Number (NZBN): 9429047031708
Certificate of Incorporation: 2716891
Registered office 14 - 16 Harbour Street, Oamaru 9400, New Zealand
Telephone: +64(0)21 222 9881 email: chair@distilledspiritsaotearoa.org.nz
DistilledSpiritsAotearoa.org.nz

(8) What is your/our industries willingness and availability to create alcohol/ethanol to assist in resource availability?

(9) What is our ability to rectify existing alcoholic products in NZ (ie Wine)

Opportunities for DSA members collaboration, discounts and supply chain efficiencies will be Stage B of the Working Group.