

19/04/2022 reference H3782

Arandee Ltd, P O Box 12448, Penrose, Auckland, 108
Rockfield Rd, Penrose Auckland. 09 579 5139, fax -.
Contact Sarah Rodgers sarah@arandee.co.nz

Global Proficiency Ltd for AsureQuality Ltd,
Unit 2/25 Mareno Rd, (P O Box 1335)
Tullamarine Vic 3043, Australia +61 3 9089
1151

Global Proficiency Ltd for AsureQuality Ltd,
Ruakura Research Centre, 10 Bisley Road,
Enderley, Hamilton 3241, P O Box 20474
Hamilton

To whom it may concern,

MAC Arandell Surface Sanitiser,

- Product description: sanitiser (ethanol)
- Product use: for food contact surfaces viz indirect contact & also for non-contact with food

"Passed AsureQuality assessment for food/beverage/dairy farm & factory food contact surfaces with residues minimised e. g. wiped (antifoam residue <1 ppm & not into milk) H3782 per conditions". This assessment was prepared by Global Proficiency Ltd using HACCP principles to determine equivalence with food standards listed below. See <http://assessedproducts.asurequality.com>. This supports food Risk Management Programmes & other endorsements that may apply to this product include MPI regulated farm dairy approval, MPI dairy factory endorsement, MPI regulated non-dairy animal product approvals, EPA HSNO-OSH-environment approval (& previously AQIS).

Conditions:

- Used per instructions, legislation, & GMP for up to food contact surfaces with residues minimised e. g. wiped (antifoam residue <1 ppm & not into milk). Usage /and carry-over to food should be minimised to ensure food function or composition are not affected, that residues are within limits and that food legislation requirements are met.
- The assessment is subject to notification of change and expires on 19/04/2027
- The full report is attached for supplier review and verification. The assessment is activated by countersigning & inclusion of assessment precautions / assessment statement / MPI dairy precautions statement (& it does not allow use of the word approval or of the AsureQuality logo).

Prepared by Global Proficiency for AsureQuality Ltd by Bob Hutchinson PhD Snr Dev Sci



Supplier:..... Date:.....

Scope and purpose of the assessment:

- Asurequality assessment is a non-regulated, voluntary, and evidential certification by the supplier demonstrating equivalence with food safety standards, and also that product instructions address hazards for staff & equipment. The assessment is independently confirmed, without prejudice or guarantee, using information submitted by the supplier or from other sources. Confidentiality of the product formulation is maintained using coded material identifiers in the report, and appendices containing confidential information are provided only to the supplier.
- Scope: NZ checks (FSANZ, US FDA 21 CFR/ NSF, Food Chemicals Codex, EPA NZ, EU, French culinary listings or related data for equivalent safety). NZ background (Animal Products Act, Risk Management Programmes. Detergent & Sanitiser Manufacturer's Code of Practice, Detergent & Sanitiser Standards and Analytical Methods. Quality Manual - Assessment Procedures

Summary of assessment with risks highlighted:

- Information status & prior registrations (Regulatory all components listed or exempt NICNAS and NZIoC. HSNO aerosol flammable HSR002515. Approvals MPI C43 all animal products including dairy. AsureQuality food beverage dairy).
- Food safety per (1) distanced to food contact surfaces residue minimised viz indirect contact, (2) ingredients below listed vs food / safety references above, (3) purity part previously & limited in epidemic vs FSANZ & FCC in the table header (4) carry over used as antifoam at 10 ppm vs USA zero in milk vs preferred food antifoam in Japan).
- QA (ISO 9000 series not necessarily required beyond CIP).
- QC specs (Chemical food safety is per raw material purities part listed. Micro safety is by sanitiser level)
- Instructions
 - Label approx abbreviated (Arandell hospital grade surface sanitiser. Fragrance free. Active constituents >70% Ethanol, kills 99.99% of germs viruses, fungi, disinfects and deodorises. MPI approved C43 all animal products including dairy). For hard and soft surfaces- kills common germs, viruses & fungi. Use on equipment & machinery high touch & high-risk areas listed & says safe on soft furnishings listed. Says effective vs germs (E coli, Salmonella cholerasuis, Staph aureus, Ps aeruginosa, Strep pyogenes). Also fungi (Aspergillus niger, Trichophyton mentagrophytes). Also viruses (Rhinovirus type 27, Influenza type A, H1N1, Human coronavirus, Poliovirus, Rotavirus, Respiratory syncytial virus, Adenovirus, Herpes simplex virus type 1 & 2). Approvals MPI C43 all animal products including dairy. AsureQuality food beverage dairy. HSNO HSR002515. Shake, spray until wet then air dry. Thoroughly drain & buff before exposure to dairy. before exposure to food products. To sanitise and condition spray liberally onto soft cloth and polish desired surfaces. To sanitise & deodorise soft furnishings patch test, mist spray & do not saturate. Not on wood, painted surfaces, leather, acrylic plastics, sealed slate or delicate fabrics. Not on therapeutic devices. Not on skin and not on food. Caution. Keep out of reach of children. Extremely flammable & list of cautions. Storage & disposal cautions. Warning list. First Aid list. Poisons Centre list. Propellant (Hydrocarbons ozone safe. Arandee contacts information.
 - SDS (Arandell surface sanitiser fragrances - fragrance free. Hazardous and Dangerous Good. risks - contains gas under pressure, may explode if heated. May cause cryogenic burns or injury. Hazard 223 Flammable aerosol. Precautions list.

Hazardous composition (Ethanol denatured SDA3A CAS 64-17-5 70-75%, Other non-hazardous CAS 6348-52-7 25-30%. Hydrocarbon propellant blend CAS 106-97-6 38.5%). Exposure (controls & limits Ethanol TWA 1880 mg/m³/8 hrs, Propane TWA 1000 ppm, Butane 1900 mg/m³/8 hrs). Properties (flash point -60C etc). Toxicology (LC50 inhalation ethanol rat 124700 mg/m³, butane 658000 mg/m³, LD50 oral rat 7g/kg. Irritation corrosion values for Ethanol. Ecology (list). Regulatory all components listed or exempt NICNAS and NZIoC. HSN0 aerosol flammable HSR002515. HSN0 # no, tracking no).

- Side effects (Environment/OSH are per SDS & EPA NZ system, & production side effects are per Raw 2 antifoam not permitted for addition to milk at least in USA etc markets but main antifoam in Japan & dealt with in instruction for soft cloth buff)
- Hygiene efficacy (Tabled in instructions and under the sanitiser active eg to FDA Monograph and studies vs Covid).

Contents (This is a simplified report with sections 2-11 replaced by a summary on p1 and in the table in section 1)

0 Information is to be evidential (std 0).	1 Materials safety and residues etc
2 Material (other – function)	3 Quality assurance certificate
4 Purity (or Design, formulation, fabrication and finish).	5 Instructions
6 Freedom from apparent side effects	7 Efficacy or hygiene to meet food safety margins
8 Packaging safety.	9 Summary of submitted information etc
10 Standards/References - front page/may be attached	11 Contacts.
12 Confidential information re design, formulation etc.	13 Covering letter & then 14 Raw material confidential information

Risk Rating (failure/accident)

	Chemical	Microbiological
Incidence	Low	Low
Susceptibility	Low	Low (higher post heat treatment)
Severity	Low	Low
Total	Low	Low (higher post heat treatment)

Organics

For organic production when food is absent during use and residues are rinsed etc. Reference NZS8410 Organic Production section 10 Storage, transport, preparation and handling. 10.1.2 Where the premises vehicles and equipment are used solely for organic products: (a) Only those substances used in table D1 shall be used for housekeeping purposes in the presence of the product (note that product absence is already a requirement of this assessment). If other materials are used for cleaning, surfaces that could come in contact with organic products shall be flushed with potable water prior to re-entry of organic products, and any airborne substance dispersed. (b) If there are products of more than one organic status (e. g. organic and in conversion to organic), the requirements of 10.1.3 shall be followed as if the higher status organic product were in the presence of products not complying with this standard. 10.1.3 (Note that If not dedicated to organics then the plan must state how there is no non-organics inclusion including "sealing, labelling, documentation").

Evaluation: Note that Standards vs. submission-responses yield compliance status in each of the sections below.

Nature of information

0 Standard: Assurance information is to be evidential/cross-registered/or ex accredited bodies (and approvals may need levels of independence for toxicity and efficacy).

- Information status & prior registrations (Regulatory all components listed or exempt NICNAS and NZIoC. HSN0 aerosol flammable HSR002515. Approvals MPI C43 all animal products including dairy. AsureQuality food beverage dairy).

Raw materials:

1 Standard:

Raw materials are to be identified safe: traceably identified, non-toxic, and pure - depending on the level of contact. Raw materials are to be safe at residue levels with safety factors (simplified here eg per cross-registration of USFDA 21 CFR/ ANZF/ EU etc registrations factored for likely equivalence and recognising high 1.5 L milk consumption would have been required by FDA etc – refers to supplier confidential appendix but with identifiers excluded

Response

(Arandee Ltd) MAC Arandell Surface Sanitiser H3782 19-04-2022	Registrations column. Scope: checks (Food Standards Australia NZ, NICNAS AICS, EPANZ NZIoC, US FDA 21 & 40 CFR/ NSF, Food Chemicals Codex, EPA NZ, EU, French culinary listings, WHO or MPI, or related data for equivalent safety). Background ("Accord", Animal Products Act, Risk Management Programmes. Detergent & Sanitiser Manufacturer's Code of Practice, Detergent & Sanitiser Standards and Analytical Methods. Quality Manual - Assessment Procedures	Purity column raw purities to be per FSANZ purity wanted (as ingredient etc) FCC7 2010-2011 with GMP indicators & FSANZ also (require Pb<2, As<1, Heavy metals <40 mg/kg). Purity column.
HACCP vs Instruction summary	Instructions label approx abbreviated (Arandell hospital grade surface sanitiser. Fragrance free. Active constituents >70% Ethanol, kills 99.99% of germs viruses, fungi, disinfects and deodorises. MPI approved C43 all animal products including dairy). For hard and soft surfaces- kills common germs, viruses & fungi. Use on equipment & machinery high touch & high-risk areas listed & says safe on soft furnishings listed. Says effective vs germs (E coli, Salmonella cholerasuis, Staph aureus, Ps aeruginosa, Strep pyogenes). Also fungi (Aspergillus niger, Trichophyton mentagrophytes). Also	SDS (Arandell surface sanitiser fragrances - fragrance free. Hazardous and Dangerous Good. risks - contains gas under pressure, may explode if heated. May cause cryogenic burns or injury. Hazard 223 Flammable aerosol. Precautions list. Hazardous composition (Ethanol denatured SDA3A CAS 64-17-5 70-75%, Other non-hazardous CAS 6348-52-7 25-30%. Hydrocarbon propellant blend CAS 106-97-6 38.5%). Exposure (controls & limits Ethanol TWA 1880 mg/m ³ /8 hrs, Propane TWA 1000 ppm, Butane 1900 mg/m ³ /8 hrs). Properties (flash point -60C etc).

	<p>viruses (Rhinovirus type 27, Influenza type A, H1N1, Human coronavirus, Poliovirus, Rotavirus, Respiratory syncytial virus, Adenovirus, Herpes simplex virus type 1 & 2). Approvals MPI C43 all animal products including dairy. AsureQuality food beverage dairy. HSNO HSR002515. Shake, spray until wet then air dry. Thoroughly drain & buff before exposure to dairy. before exposure to food products. To sanitise and condition spray liberally onto soft cloth and polish desired surfaces. To sanitise & deodorise soft furnishings patch test, mist spray & do not saturate. Not on wood, painted surfaces, leather, acrylic plastics, sealed slate or delicate fabrics. Not on therapeutic devices. Not on skin and not on food. Caution. Keep out of reach of children. Extremely flammable & list of cautions. Storage & disposal cautions. Warning list. First Aid list. Poisons Centre list. Propellant (Hydrocarbons ozone safe. Arandee contacts information.</p>	<p>Toxicology (LC50 inhalation ethanol rat 124700 mg/m3, butane 658000 mg/m3, LD50 oral rat 7g/kg. Irritation corrosion values for Ethanol. Ecology (list). Regulatory all components listed or exempt NICNAS and NZIoC. HSNO aerosol flammable HSR002515. HSNO # no, tracking no).</p>
HACCP analysis of other aspects	<p>Information status & prior registrations (Regulatory all components listed or exempt NICNAS and NZIoC. HSNO aerosol flammable HSR002515. Approvals MPI C43 all animal products including dairy. AsureQuality food beverage dairy). Food safety per (1) distanced to food contact surfaces residue minimised viz indirect contact, (2) ingredients below listed vs food / safety references above, (3) purity part previously & limited in epidemic vs FSANZ & FCC in the table header (4) carry over used as antifoam at 10 ppm vs USA zero in milk vs preferred food antifoam in Japan). QA (ISO 9000 series not necessarily required beyond CIP). QC specs (Chemical food safety is per raw material purities part listed. Micro safety is by sanitiser level)</p>	<p>Side effects (Environment/OSH are per SDS & EPA NZ system, & production side effects are per Raw 2 antifoam not permitted for addition to milk at least in USA etc markets but main antifoam in Japan & dealt with in instruction for soft cloth buff) Hygiene efficacy (Tabled in instructions and under the sanitiser active eg to FDA Monograph and studies vs Covid).</p>
Raw 1 solvent / sanitiser	<p>NICNAS AICS listed as not assessed. EPA NZ under HSR number. EPA NZ Cosmetic list not returned. FSANZ FS Code & 21CFR (Commonly used foodstuff Anti-microbial agent, extraction solvent, vehicle in pizza crust. Regulated per USA FDA 21 CFR 184.1293, GRAS to 2% in pizza crust per GMP. Toxicity: (data in Wikipedia Also CTFA listed. EPA genetic tox programme. OSHA PEL: TWA 1000 ppm ACGIH TLV: TWA 1000 ppm DFG MAK: 1000 ppm (1,900 mg/m3). Safety Profile - moderately toxic to humans by ingestion. Mod toxic experimentally by iv and intra-peritoneal route. Mildly toxic by inhalation and skin contact. Experimental tumorigen and teratogen. Human systemic effect). Efficacy (" Alcohol rub sanitizers containing at least 70% alcohol, kill 99.9% of the bacteria on hands 30 seconds after application and 99.99% to 99.999%[note 1] in one minute.[4] For health care settings like hospitals and clinics, optimum alcohol concentration to kill germs is 70% to 95%.[35][36]</p>	<p>Efficacy continued ("Alcohols" chapter of Block It is probably not possible to sterilise the skin, the best one can hope to accomplish is to reduce the number of viable organisms on or in the skin and to destroy the pathogenic organisms that may be on the skin as transients. Hatfield and Lockwood 1943 concluded 70-95% was preferable. Price 1938 described bacteria as transients and residents and Evans1980 observed that in 15 individuals with sparse flora in the ante-cubital fossa, no surviving bacteria were detected after alcohol treatment for 60 seconds, but in 10 individuals with more abundant flora, viable bacteria remained with no correlation with surface flora. Price1939 found ethyl alcohol at 65.5% x 1 minute's contact was as effective as scrubbing for 4.2 minutes. There may be different effects for transient and resident organisms. The loss of skin antibacterial properties results in a bacterial increase in moist (under patch) conditions but otherwise there is continued population loss for several hours from organisms terminally damaged).</p>
Raw 1 continued.	<p>(Efficacy continued) The 1977 Rotter method used by German and Austrian governments uses E coli artificial challenge with 4 log or greater reduction for alcohols vs 2-3 log reduction for soaps for 70% alcohol equivalence. Lacey 1968 demonstrated re-growth from removal of skin anti-bacterials which Larson showed was reversed at say 4-hour gloving with 0.5% chlorhexidine, and Lowbury et al 1979 noted die-off for several hours. Other sections show it is not adversely affected by use of methylated spirits. Not effective against spores. At 70-90% inactivated all viruses of 7 general types especially those with a lipid envelope.</p>	<p>(Efficacy continued) Dryness of hands will reduce microbial transfer 100x (per Dr Tom Miller, Auckland Hospital). 21 CFR accepts 60-95% for patient prep - as opposed to surgeons use preparatory to gloves (short term as opposed to medium 6-hour type use refer USA FDA 21CFR 333, & 369 Tentative final monograph for healthcare antiseptic drug products; proposed rule.) Efficacy vs covid etc virus 62-71% ethanol, 0.5% hydrogen peroxide or 0.1% sodium hypochlorite within 1 minute (refer J Hospital Infection 104 (2020) 246-25). Also alcohol 71% - G. Kampf a, *, D. Todt b, S. Pfaender b, E. Steinmann Elsevier 2020. Purity wanted (is per the column header & FCC adds Pb <0.5 mg/kg, fusel oil - nil by odour, ketones, isopropanol & methanol, substances darkened by sulphuric acid & reducing permanganate all nil by test. Acidity <0.003% etc). Purity found (not found, varying source during Covid. Arandee add when settled)</p>
Raw 1 denaturant	<p>USFDA21CFR 173.250 limited to 50 ppm in spice oleoresins, & 2.2% in hops extracts as extraction solvent. Also FSANZ & 21CFR 2% of antifoam permitted to 10 mg/kg.</p>	<p>Purity n/a</p>
Raw 2 silicone polymer	<p>NICNAS AICS returned use with no 2nd notification. NZIoC HSR003036 or 6679 in non-hazardous diluent. FSANZ prohibits for contact substances other than listed (1) 1.3.3.4 permitted antifoam to 10 mg/kg FOUND & (92) 1.3.3.9 permitted lubricant, release agent & anti-</p>	<p>181.28 110 mg/kg in gelatin, zero tolerance in milk, & as lubricant <1 mg/kg residue, 9CFR318.7, 381.147 - the lubricants are used on food processing equipment as a protective ant-rust film, as a release agent on gaskets or seals of tank closures, and as a lubricant</p>

	stick NOT FOUND. 21CFR 178.3570 Dimethylpolysiloxane (viscosity greater than 300 centistokes). Addition to food not to exceed 1 part per million (& not added to milk).	for machine parts and equipment where there is exposure of the lubricated part to food. The amount used is the minimum required to accomplish the desired technical effect on the equipment, and the addition to food of any constituent identified in this section does not exceed the limitations prescribed viz. the addition of silicone to food does not exceed 1 mg/kg. USA uses include defoamer, hog & poultry scald, & release agent. Purity wanted (per column header). Purity found (previously got - for regulated applications - food contact, raw material for medical devices, & pharmacy & properties found listed). .
Raw 3 propellant gas.	NZIoC HSR001009. AICS human health tier 2 no secondary notification required. FSANZ FS Code (1.3.3 Miscellaneous additives permitted in accordance with GMP in processed foods specified in the schedule & this cross-credits to processing aids). USA FDA (21CFR174.1655 GRAS with GMP for purpose of aerating agent, gas, propellant used variously).	Toxicity (OSHA PEL TWA 1000 ppm, etc. Flammable gas label flammable gas. Safety central nervous system effects at high concentrations. An asphyxiant flammable gas etc). Purity wanted (per column header). Purity found (previously got - specified very light paraffinics & beyond this may not be critical for incidental contact).
Ingredient sum got 100%/100% agrees)		
pH & water activity in micro growth ranges	pH growth ranges: B cereus 4.4-9.3, Campylobacter jejuni 4.9-9.0, C botulinum A & B 4.8-8.5 type E 5-8.5, C perfringens 5-8.9, Listeria monocytogenes 4.5-8.0, Salmonella 3.8-9,	Staph aureus 4.3-9.0, vibrio cholerae 6-11, vibrio parahaemolyticus 4.8-9, vibrio vulnificus 5-10, Yersinia enterocolitica 4.4-9.6

--	--	--	--	--	--	--	--	--	--

- Food safety per (1) distanced to food contact surfaces residue minimised viz indirect contact, (2) ingredients below listed vs food / safety references above, (3) purity part previously & limited in epidemic vs FSANZ & FCC in the table header (4) carry over used as antifoam at 10 ppm vs USA zero in milk vs preferred food antifoam in Japan).
- **The formulation in confidence follows & is not for public circulation**

12 The formulation in confidence follows & is not for public circulation

<p>(Arandee Ltd) MAC Arandell Surface Sanitiser H3782 19-04-2022</p>	<p>Registrations column. Scope: checks (Food Standards Australia NZ, NICNAS AICS, EPANZ NZIoC, US FDA 21 & 40 CFR/ NSF, Food Chemicals Codex, EPA NZ, EU, French culinary listings, WHO or MPI, or related data for equivalent safety). Background ("Accord", Animal Products Act, Risk Management Programmes. Detergent & Sanitiser Manufacturer's Code of Practice, Detergent & Sanitiser Standards and Analytical Methods. Quality Manual - Assessment Procedures</p>	<p>Purity column raw purities to be per FSANZ purity wanted (as ingredient etc) FCC7 2010-2011 with GMP indicators & FSANZ also (require Pb<2, As<1, Heavy metals <40 mg/kg). Purity column.</p>
<p>HACCP vs Instruction summary & exception reporting (Formulation detail over-estimates carryover 100x? per the standard farm CIP model)</p>	<p>Instructions label approx abbreviated (Arandell hospital grade surface sanitiser. Fragrance free. Active constituents >70% Ethanol, kills 99.99% of germs viruses, fungi, disinfects and deodorises. MPI approved C43 all animal products including dairy). For hard and soft surfaces- kills common germs, viruses & fungi. Use on equipment & machinery high touch & high-risk areas listed & says safe on soft furnishings listed. Says effective vs germs (E coli, Salmonella cholerasuis, Staph aureus, Ps aeruginosa, Strep pyogenes). Also fungi (Aspergillus niger, Trichophyton mentagrophytes). Also viruses (Rhinovirus type 27, Influenza type A, H1N1, Human coronavirus, Poliovirus, Rotavirus, Respiratory syncytial virus, Adenovirus, Herpes simplex virus type 1 & 2). Approvals MPI C43 all animal products including dairy. AsureQuality food beverage dairy. HSNO HSR002515. Shake, spray until wet then air dry. Thoroughly drain & buff before exposure to dairy. before exposure to food products. To sanitise and condition spray liberally onto soft cloth and polish desired surfaces. To sanitise & deodorise soft furnishings patch test, mist spray & do not saturate. Not on wood, painted surfaces, leather, acrylic plastics, sealed slate or delicate fabrics. Not on therapeutic devices. Not on skin and not on food. Caution. Keep out of reach of children. Extremely flammable & list of cautions. Storage & disposal cautions. Warning list. First Aid list. Poisons Centre list. Propellant (Hydrocarbons ozone safe. Arandee contacts information.</p>	<p>SDS (Arandell surface sanitiser fragrances - fragrance free. . Hazardous and Dangerous Good. risks - contains gas under pressure, may explode if heated. May cause cryogenic burns or injury. Hazard 223 Flammable aerosol. Precautions list. Hazardous composition (Ethanol denatured SDA3A CAS 64-17-5 70-75%, Other non-hazardous CAS 6348-52-7 25-30%. Hydrocarbon propellant blend CAS 106-97-6 38.5%). Exposure (controls & limits Ethanol TWA 1880 mg/m3/8 hrs, Propane TWA 1000 ppm, Butane 1900 mg/m3/8 hrs). Properties (flash point -60C etc). Toxicology (LC50 inhalation ethanol rat 124700 mg/m3, butane 658000 mg/m3, LD50 oral rat 7g/kg. Irritation corrosion values for Ethanol. Ecology (list). Regulatory all components listed or exempt NICNAS and NZIoC. HSNO aerosol flammable HSR002515. HSNO # no, tracking no).</p>
<p>HACCP analysis of other aspects</p>	<p>Information status & prior registrations (Regulatory all components listed or exempt NICNAS and NZIoC. HSNO aerosol flammable HSR002515. Approvals MPI C43 all animal products including dairy. AsureQuality food beverage dairy). Food safety per (1) distanced to food contact surfaces residue minimised viz indirect contact, (2) ingredients below listed vs food / safety references above, (3) purity part previously & limited in epidemic vs FSANZ & FCC in the table header (4) carry over used as antifoam at 10 ppm vs USA zero in milk vs preferred food antifoam in Japan). QA (ISO 9000 series not necessarily required beyond CIP). QC specs (Chemical food safety is per raw material purities part listed. Micro safety is by sanitiser level)</p>	<p>Side effects (Environment/OSH are per SDS & EPA NZ system, & production side effects are per Raw 2 antifoam not permitted for addition to milk at least in USA etc markets but main antifoam in Japan & dealt with in instruction for soft cloth buff) Hygiene efficacy (Tabled in instructions and under the sanitiser active eg to FDA Monograph and studies vs Covid).</p>
<p>Ethanol CAS 64-17-5 from - x70% w/w9(?) Raw 1 solvent</p>	<p>NICNAS AICS listed as not assessed. EPA NZ under HSR number. EPA NZ Cosmetic list not returned. FSANZ FS Code & 21CFR (Commonly used foodstuff Anti-microbial agent, extraction solvent, vehicle in pizza crust. Regulated per USA FDA 21 CFR 184.1293, GRAS to 2% in pizza crust per GMP. Toxicity: (data in Wikipedia Also CTFA listed. EPA genetic tox programme. OSHA PEL: TWA 1000 ppm ACGIH TLV: TWA 1000 ppm DFG MAK: 1000 ppm (1,900 mg/m3). Safety Profile - moderately toxic to humans by ingestion. Mod toxic experimentally by iv and intra-peritoneal route. Mildly toxic by inhalation and skin contact. Experimental tumorigen and teratogen. Human systemic effect). Efficacy (" Alcohol rub sanitizers containing at least 70% alcohol, kill 99.9% of the bacteria on hands 30 seconds after application and 99.99% to 99.999%[note 1] in one minute.[4] For health care settings like hospitals and clinics, optimum alcohol concentration to kill germs is 70% to 95%.[35][36]</p>	<p>Efficacy continued ("Alcohols" chapter of Block It is probably not possible to sterilise the skin, the best one can hope to accomplish is to reduce the number of viable organisms on or in the skin and to destroy the pathogenic organisms that may be on the skin as transients. Hatfield and Lockwood 1943 concluded 70-95% was preferable. Price 1938 described bacteria as transients and residents and Evans1980 observed that in 15 individuals with sparse flora in the ante-cubital fossa, no surviving bacteria were detected after alcohol treatment for 60 seconds, but in 10 individuals with more abundant flora, viable bacteria remained with no correlation with surface flora. Price1939 found ethyl alcohol at 65.5% x 1 minute's contact was as effective as scrubbing for 4.2 minutes. There may be different effects for transient and resident organisms. The loss of skin antibacterial properties results in a bacterial increase in moist (under patch) conditions but otherwise there is continued population loss for several hours from organisms terminally damaged).</p>
<p>Raw 1 continued.</p>	<p>(Efficacy continued) The 1977 Rotter method used by German and Austrian governments uses E coli artificial challenge with 4 log or greater reduction for alcohols vs 2-3 log reduction for soaps for 70% alcohol equivalence. Lacey 1968 demonstrated re-growth from removal of skin anti-bacterials which Larson showed was reversed</p>	<p>(Efficacy continued) Dryness of hands will reduce microbial transfer 100x (per Dr Tom Miller, Auckland Hospital). 21 CFR accepts 60-95% for patient prep - as opposed to surgeons use preparatory to gloves (short term as opposed to medium 6-hour type use refer USA FDA 21CFR 333, & 369 Tentative final</p>

	at say 4-hour gloving with 0.5% chlorhexidine, and Lowbury et al 1979 noted die-off for several hours. Other sections show it is not adversely affected by use of methylated spirits. Not effective against spores. At 70-90% inactivated all viruses of 7 general types especially those with a lipid envelope.	monograph for healthcare antiseptic drug products; proposed rule.) Efficacy vs covid etc virus 62-71% ethanol, 0.5% hydrogen peroxide or 0.1% sodium hypochlorite within 1 minute (refer J Hospital Infection 104 (2020) 246-25). Also alcohol 71% - G. Kampf a, *, D. Todt b, S. Pfaender b, E. Steinmann Elsevier 2020. Purity wanted (is per the column header & FCC adds Pb <0.5 mg/kg, fusel oil - nil by odour, ketones, isopropanol & methanol, substances darkened by sulphuric acid & reducing permanganate all nil by test. Acidity <0.003% etc). Purity found (not found, varying source during Covid. Arandee add when settled)
Raw 1 continued has Methanol CAS 006-75-61 from - 70% x 5% is 3.5% w/w (?) Raw 1 denaturant	USFDA21CFR 173.250 limited to 50 ppm in spice oleoresins, & 2.2% in hops extracts as extraction solvent. Also FSANZ & 21CFR 2% of antifoam permitted to 10 mg/kg.	Purity n/a
Linear Polydimethylsiloxane CAS 91052-96-9 EPA NZ listed & HSR003036 from - x 0.5% w/w Raw 2 silicone polymer	NICNAS AICS returned use with no 2nd notification. NZIoC HSR003036 or 6679 in non-hazardous diluent. FSANZ prohibits for contact substances other than listed (1) 1.3.3.4 permitted antifoam to 10 mg/kg FOUND & (92) 1.3.3.9 permitted lubricant, release agent & anti-stick NOT FOUND. 21CFR 178.3570 Dimethylpolysiloxane (viscosity greater than 300 centistokes). Addition to food not to exceed 1 part per million (& not added to milk).	181.28 110 mg/kg in gelatin, zero tolerance in milk, & as lubricant <1 mg/kg residue, 9CFR318.7, 381.147 - the lubricants are used on food processing equipment as a protective ant-rust film, as a release agent on gaskets or seals of tank closures, and as a lubricant for machine parts and equipment where there is exposure of the lubricated part to food. The amount used is the minimum required to accomplish the desired technical effect on the equipment, and the addition to food of any constituent identified in this section does not exceed the limitations prescribed viz. the addition of silicone to food does not exceed 1 mg/kg. USA uses include defoamer, hog & poultry scald, & release agent. Purity wanted (per column header). Purity found (previously got - for regulated applications - food contact, raw material for medical devices, & pharmacy & properties found listed). .
Propellant Propane/ butane CAS 91052-98-9 , 68551-21-3 from Rockgas NZ Ltd. X 29.5 w/w Raw 3 propellant gas.	NZIoC HSR001009. AICS human health tier 2 no secondary notification required. FSANZ FS Code (1.3.3 Miscellaneous additives permitted in accordance with GMP in processed foods specified in the schedule & this cross-credits to processing aids). USA FDA (21CFR174.1655 GRAS with GMP for purpose of aerating agent, gas, propellant used variously).	Toxicity (OSHA PEL TWA 1000 ppm, etc. Flammable gas label flammable gas. Safety central nervous system effects at high concentrations. An asphyxiant flammable gas etc). Purity wanted (per column header). Purity found (previously got - specified very light paraffinics & beyond this may not be critical for incidental contact).
Ingredient sum got 100%/100% agrees)		
pH & water activity in micro growth ranges	pH growth ranges: B cereus 4.4-9.3, Campylobacter jejuni 4.9-9.0, C botulinum A & B 4.8-8.5 type E 5-8.5, C perfringens 5-8.9, Listeria monocytogenes 4.5-8.0, Salmonella 3.8-9,	Staph aureus 4.3-9.0, vibrio cholerae 6-11, vibrio parahaemolyticus 4.8-9, vibrio vulnificus 5-10, Yersinia enterocolitica 4.4-9.6

--	--	--	--	--	--	--	--	--	--	--

19/04/2022 reference H3782

Arandee Ltd, P O Box 12448, Penrose, Auckland, 108
Rockfield Rd, Penrose Auckland. 09 579 5139, fax -.
Contact Sarah Rodgers sarah@arandee.co.nz

Global Proficiency Ltd for AsureQuality Ltd,
Unit 2/25 Mareno Rd, (P O Box 1335)
Tullamarine Vic 3043, Australia +61 3 9089
1151

Global Proficiency Ltd for AsureQuality Ltd,
Ruakura Research Centre, 10 Bisley Road,
Enderley, Hamilton 3241, P O Box 20474
Hamilton

Dear Sarah,

Please find attached your assessment report and I hope it is as you wanted or please let us know any questions or suggestions and the invoice and web listing should follow.

Just a heads up that this AQ service is under review for major change pending discussion with MPI. I do not know more than that including timing - but it may use direct access through to MPI and possibly static AQ website for 5 years (?). Thanks for this.

MAC Arandell Surface Sanitiser

- Product description: sanitiser (ethanol)
- Product use: for food contact surfaces viz indirect contact & also for non-contact with food
- Status: passed AsureQuality farm & factory assessment renewed cost \$184.16 + GST for 1:05 hours. NB the source of chemicals & purity is wanted for contact surfaces but not critical here per zero food residue indicated in request).

"Passed AsureQuality assessment for food/beverage/dairy farm & factory food contact surfaces with residues minimised e. g. wiped (antifoam residue <1 ppm & not into milk) H3782 per conditions". This assessment was prepared by Global Proficiency Ltd using HACCP principles to determine equivalence with food standards listed below. See <http://assessedproducts.asurequality.com>. This supports food Risk Management Programmes & other endorsements that may apply to this product include MPI regulated farm dairy approval, MPI dairy factory endorsement, MPI regulated non-dairy animal product approvals, EPA HSNO-OSH-environment approval (& previously AQIS).

Conditions:

- Used per instructions, legislation, & GMP for up to food contact surfaces with residues minimised e. g. wiped (antifoam residue <1 ppm & not into milk). Usage /and carry-over to food should be minimised to ensure food function or composition are not affected, that residues are within limits and that food legislation requirements are met.
- The assessment is subject to notification of change and expires on 19/04/2027.
- The full report is attached for supplier review and verification. The assessment is activated by countersigning & inclusion of assessment precautions / assessment statement / MPI dairy precautions statement (& it does not allow use of the word approval or of the AsureQuality logo).

Prepared by Global Proficiency for AsureQuality Ltd by Bob Hutchinson PhD Snr Dev Sci

