

30/04/2018 Reference H2136

Safe4 All NZ (2015) Ltd P O Box 875, Rangiora 7440, Ph 027 224 3644 Contact Kirsty Mathieson 4info@safe4all.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,

Safe4 Disinfectant Cleaner

- Product description: disinfectant,
- Product use: all animal facilities, including zoos, vets, pet boarding, including cats,

"Passed AsureQuality assessment for food/ beverage/ dairy pet food contact surfaces with residues drained & minimised e.g. safe rinsed and avoiding contact with mucous membranes" H2136 with 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 pet food contact surfaces with residues drained & minimized e.g. safe rinsed.
- Use / carry-over to food should be minimised to ensure food function or composition are not affected, that residues are within applicable Maximum Residue Limits and that food legislation requirements are met.
- The assessment is subject to notification of change and expires on 30/04/2023.
- The full report is attached for supplier review and verification. The assessment is activated by countersigning

Prepared by Global Proficiency for AsureQuality Ltd by Bob Hutchinson PhD SENIOR DEVELOPMENT SCIENTIST.

Supplier:....

Reg Hulchinson

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.

Date:....

 Scope: NZ checks (NICNAS AICS. 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 any risks highlighted:

- Information and prior assessments (Renewed AsureQuality assessment see table of efficacy http://www.safe4 disinfectant/test results/safe 4 test results table.pdf - also DEFRA General Orders - Animal Diseases viz 10000x reduction of Salmonella cholerae suis NCTC10653 /5% yeast soil/4C/30 mins. DEFRA Diseases of Poultry & DEFRA Tuberculosis Order HSR002530 cleaning products subsidiary hazard. All components on NZIoC).
- Food-safety (per food listings FSANZ/ FDA 21 CFR/ Alimentary Standard slightly incomplete formulation here and no apparent raw material risk based on an approximate formulation in the SDS).
- QA, to ISO 9000 series and QC are not required for low contact here except raw IDs are mostly, not all, completed safe & QAC sanitiser present see safety table).
- Instructions example (see table of use rates, use conditions, diseases & test results in the report table. http://www.safe4disinfectant/test results/safe 4 test results table.pdf - also DEFRA General Orders - Animal Diseases viz 10000x reduction of Salmonella cholerae suis NCTC10653 /5% yeast soil/4C/30 mins. DEFRA Diseases of Poultry & DEFRA Tuberculosis Order).
- SDS (Sections on identifiers for product & company, Hazards EC listings. labelling, contains Benzyl alkyldimethylammonium chloride, Alkylpolyethoxylate, & Ethylene diamine. Pictogram, Signal - Danger H318 causes serious eye damage, H315 causes skin irritation, EU H208 contains polyhexamethylene biguanide may cause allergic reaction. Composition with Ingredients with % range, CAS, EC No, REACH no, & hazard statements (Benzyl alkyl dimethyl ammonium chloride 3-5% hazards, Polyhexamethylene biguanide HCI <1%, Alkyl C9-11 polyethoxylate 3-7%, Dipropylene glycol monomethyl ether 1-5%, EDTA 1-5%, Phosphoric acid <0.5%, Apple FAF229 <0.5%, Hexacol Blue/Green-7759 <0.5%, & Water >75%. Various SDS panel lists. Exposure controls (precautions plus Dipropylene glycol monomethyl ether TWA 308 mg/m3. Properties (pH 7-8 etc), Toxicology (similar to hazards with chronic values not classified). Ecology (is detailed). Transport (not-DG), Regulatory (Biodegradation complies with EC 648/2004 on detergents).
- Unwanted effects (Per SDS, HSNO EPA NZ NZIoC listed ingredients etc. Danger H318 causes serious eye damage, H315 causes skin irritation, EU H208 w/o product listing (?). Production side effects per low level indirect contact).
- Hygiene efficacy (is as above per table and website lab kill data in the word report immediately below)



Microorganism	Dilution	Contact time mins	Log reduction	Tested by	Test protocol	Test date	Result
Microbactericidal data							
Mycobacterium avium	1:40	60	5	Abbott Analytical	EN14204	21/11/05	Pass
Mycobacterium bovis	1:40	30	5	Abbott Analytical	EN14348	06/03/06	Pass
Virucidal activity							
Canine parvovirus	1:50	5	3.75	BluScientific		06/03/06	Pass
Canine parvovirus	1:50	5	>4	BluScientific	EN14476	18/10/2010	Pass
Canine parvovirus & low cytotoxicity	1:100	30	3.33	BluScientific	EN14476	18/10/2010	Pass
Feline calcivirus	1:20	5	>4	BluScientific	EN14476		Pass
Feline immunodeficiency virus	1:50	5	3.1	BluScientific		10/02/06	Pass
Feline leukaemia virus	1:100	5	3.5	BluScientific		10/02/06	Pass
Fungicidal activity							
Candida albicans	1:100	15	6	Abbott Analytical	EN1275	10/11/05	Pass
Microsporum canis	1:100	60	5	Abbott Analytical	EN1675	10/11/05	Pass
Trichophyton mentagrophytes	1:100	60	5	Abbott Analytical	EN13624	10/11/05	Pass
Bactericidal activity							
Methcillin resistant Staph aureus	1:300	5	5.11	Abbott Analytical	EN12676	10/11/05	Pass
Pseudomonas aeruginosa	1:300	5	3	Abbott Analytical	EN12676	10/11/05	Pass
Listeria monocytogenes	1:200	5	6	Abbott Analytical	EN12676	10/11/05	Pass
Campylobacter jejuni	1:200	5	6	Abbott Analytical	EN12676	10/11/05	Pass
E coli	1:300	5	6	Abbott Analytical	EN12676	10/11/05	Pass
Staph aureus	1:300	5	5	Abbott Analytical	EN12676	10/11/05	Pass
Salmonella typhimurium	1:300	5	6	Abbott Analytical	EN12676	10/11/05	Pass
Clostridium perfringens	1:20	69	4	Abbott Analytical	EN12676	23/11/05	Pass

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 (standard 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
Severity	Low	Low
Total	Low	Low

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 and prior assessments (Renewed AsureQuality assessment - see table of efficacy - http://www.safe4 disinfectant/test results/safe 4 test results table.pdf - also DEFRA General Orders - Animal Diseases viz 10000x reduction of Salmonella cholerae suis NCTC10653 /5% yeast soil/4C/30 mins. DEFRA Diseases of Poultry & DEFRA Tuberculosis Order HSR002530 cleaning products subsidiary hazard. All components on NZIoC).

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

(Safe4) Safe4 Disinfectant Cleaner H2136 30-04-2018	Registrations column. Scope: NZ checks (NICNAS AICS. 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	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 & the extra table has concentrations & carryovers where pertinent	Instructions example (see table of use rates, use conditions, diseases & test results in the report table. http://www.safe4disinfectant/test results/safe 4 test results table.pdf - also DEFRA General Orders - Animal Diseases viz 10000x reduction of Salmonella cholerae suis NCTC10653 /5% yeast soil/4C/30 mins. DEFRA Diseases of Poultry & DEFRA Tuberculosis Order).	SUS (Sections on identifiers for product & company, Hazards EC listings. labelling, contains Benzyl alkyldimethylammonium chloride, Alkylpolyethoxylate, & Ethylene diamine. Pictogram, Signal - Danger H318 causes serious eye damage, H315 causes skin irritation, EU H208 contains polyhexamethylene biguanide may cause allergic reaction. Composition with Ingredients with % range, CAS, EC No, REACH no, & hazard statements (Benzyl alkyl dimethyl ammonium chloride 3-5% hazards, Polyhexamethylene biguanide HCl <1%, Alkyl C9-11 polyethoxylate 3- 7%, Dipropylene glycol monomethyl ether 1-5%, EDTA 1-5%, Phosphoric acid <0.5%, Apple FAF229 <0.5%, Hexacol Blue/Green-7759 <0.5%, & Water >75%. Various SDS panel lists. Exposure controls (precautions plus Dipropylene glycol monomethyl ether TWA 308 mg/m3. Properties (pH 7-8 etc), Toxicology (similar to hazards with chronic values not classified). Ecology (is detailed). Transport (not-DG), Regulatory (Biodegradation complies with EC 648/2004 on detergents).
HACCP analysis of other aspects	Information and prior assessments (Renewed AsureQuality assessment see table of efficacy - http://www.safe4 disinfectant/test results/safe 4 test results table.pdf - also DEFRA General Orders - Animal Diseases viz 10000x reduction of Salmonella cholerae suis NCTC10653 /5% yeast soil/4C/30 mins. DEFRA Diseases of Poultry & DEFRA Tuberculosis Order HSR002530 cleaning products subsidiary hazard. All components on NZIoC). Food-safety (per food listings FSANZ/ FDA 21 CFR/ Alimentary Standard slightly incomplete formulation here - and no apparent raw material risk based on an approximate formulation in the SDS). QA, to ISO 9000 series and QC are not required for low contact here except raw IDs are mostly, not all, completed safe & QAC sanitiser present see safety table)	Unwanted effects (Per SDS, HSNO EPA NZ NZIoC listed ingredients etc Danger H318 causes serious eye damage, H315 causes skin irritation, EU H208 w/o product listing (?). Production side effects per low level indirect contact). Hygiene efficacy (is as above per table and website lab kill data in the word report)
Composition 100% carry over per farm model	All components listed or exempt EPA NZ NZIoC per HSNO Reg Section. Purities here may be more detailed than risk	Purity wanted (per column header). Purity found: (Unfound this time but previously white granules,
Raw 1 Sanitiser QAC	NICNAS AICS Listings (found recorded "not assessed"?) NZIoC under group standard. EU Limit 0.5 mg/kg. Proposed 0.1 mg/kg which can apply to Milkpowder & implication of a 7x lower limit in milk may not now apply. FSANZ FS Code (Unfound/unscoped?). USA FDA (21 CFR 178.1010 found to 200 ppm as sanitisers of food contact surfaces, no excess, drained, and not necessarily rinsed or extended to dairys alkyl (C12-18) benzyldimethylammonium chloride compounds with mw 351-380, alkyl mainly C12-16 <1% C8-10, may add ethanol or isopropanol, non-dairy & up 200 ppm in use solution & other countries which may require rinsing) antimicrobial agent in beets sugarcane, & regulated per FDA21CFR 18172.165 to 0.25 - 1.0 ppm), EU register (2032/2003 16(2). EPA (Classification 5-25% 6.1D (oral) Acutely toxic 6.5A (respiratory) Respiratory sensitisers 6.5B (contact)	Levis (Skin and eye irritant skin rabbit 1 mg/24H+, eye rabbit 1mg.NEL was 0.25%+ (2500 ppm+) in a 2-year rat feeding trial (Alfredson BV 1951 "Toxicity studies on alkyldimethylbenzylammonium chloride in rats and dogs" J Am Pharm Assoc 40, 263-287) etc per Block "Antiseptics and disinfectants"). Side effects (ERMA scope, +IDF Bull 288 includes production also per food listings & Residue Reviews cheese effect at 5-20 mg/kg). Efficacy Block - (Antimicrobial profile mg/L E coli 200, Ps fluorescens 300, B subtilis 3, Fungi Aspergillus niger 60, C Globosum 10, M Verrucaria 40, L viridae 40, Algae Ch vularis 1, Stigeocloneum 0.7, Os Tenuis 0.6mg/L). Purity wanted (per column header). Purity found (Unfound and may not be critical here).

AsureQuality assessment by Global Proficiency for AsureQuality Ltd, ref H2136. Page 3 of a 7 page report + an extra cover letter page Ruakura Research Centre, Hamilton East, P O Box 20474 Hamilton, New Zealand 3241 Ph +64 7 850 4483, fax+64 7 850 4487, http://assesdeproducts.asurequality.com/

	Contact sensitisers 6.9B (dermal) Harmful to human target organs or systems 8.2C. Corrosive to dermal tissue 8.3A	
	Corrosive to ocular tissue 9.1B (fish) Very ecotoxic in the	
	aquatic environment 9.1B (crustacean) Very ecotoxic in the	
	aquatic environment 9.3C Harmful to terrestrial	
	vertebrates) ANZFA(no-n/a), EU register (2032/2003	
Raw 2 Antimicrobial	Not found on EPA NZ cosmetic prohibited list. NICNAS	UK North Sea oil - UK sector/data to Min of
	AICS previously unlisted. unavailable. NZIoC as a single	Energyin cat 2. USA/Preservation of silicones,
	www.federalregister.gov/articles/2008/01/09/E8-189/	No 10182-128. Est reg no 10182-MA-01 notice
	"name" -exemption-from-the-requirement-of-a-tolerance.	1989oil recovery systems/Amendment to ESA
	This includes milk tankers as an extreme test. It is also	approval 1990. Toxicity: polyhexamethylene
	widely used on sutures (Figure 1) and in medical	biguanide (CH2)3-NH-C(=NH)-NH-(CH2)3-)12.HCl
	com/view article/561512 3. Australia/sanitiser for	list of defended substances 1997 re EU CR 434.97
	breweries/approved no specific regulations. NICNAS PECS	extended MRL dead-line. It has an uncomplicated
	no, & AICS found unassessed. Brazil/sanitiser for food	NOEL of 35+ mg/kg/day equivalent to equivalent to
	CISAD. Canada/sanitiser for food handling equipment/	chlorhexidine toxicological ADI 0-0.005 mg/kg/day
	June 1975, without rinse if used at 100 ppm or less.	is per toxicity from degradation to chloraniline.
	Denmark/sanitiser for food handling equipment/1977 May/J	Degradation components from PHMB appear
	Germany/sanitiser for food handling equipment provided	to food listed materials. Purity wanted (per column
	no residues remain. Allowed with rinse. No specific	header). Purity found (Unfound and may not be
	approval. New Zealand/sanitiser for dairy factories, for	critical here).
	0.1% with rinse/other 1979, cleared with rinse. Sth	
	Africa/disinfectant in breweries/approved no specific regs.	
	Spain/sanitiser for food handling equipment/1977 Reg	
	and Nat resources certain conditions. April 1983.	
Raw 3 on-ionic surfactant	Similar has NICNAS AICS listed w/o concern. EPA NZ	FSANZ Food Standards Code 1.3.3.3 processing
alkyl ethoxylate.	listed HSR00xxxx ok. USAFDA21CFR178.1010 - FOUND -	aids generally - FOUND.P Side effects are ok per
	an average 8-9 moles of ethylene oxide and an average	Efficacy is per BS 5750 and IDF 9101. & 9701
	molecular weight of 400. Per 21CFR178.1010 - for food	listings. Purity wanted (per column header inc
	and milk containers but not as a final rinse. Also similar to	FCC list). Purity found (Unfound and may not be
	condensation of C11-13 straight chain randomly	childa here).
	substituted secondary alcohols with an average of 7-20	
	moles of ethylene oxide. For emulsifiers and or surface-	
	compare 21 CFR173.315.	
Raw 4 polyether	NICNAS AICS listed unassessed. EPA HSR00xxxx w/o	Purity wanted (per column header & US FCC 7
	similar listing & 21 CFR 178.1010 & similar 178.3400 etc	not be critical here).
	bridging listings. Includes safe glycol dimer & methyl	
	terminated & protected vs C2 stripping of terminal alkyl	
	direct food ingredient e.g. in chewing gum.	
Raw 5 Sequestrant	NICNAS AICS listed as not assessed. EPA NZ under	Poison by intravenous, moderately toxic by
	HSR00xxxx. 21 CFR 173. 310 "secondary direct food	ingestion, experimental reproductive and
	.310 "boiler water additives not in excess and listed in the	generally and ex BASF it is not absorbed, excreted
	section). Also has registered uses as hog scald	inside 24 hours, with no carcinogenic, mutagenic,
	sequestrant and stabiliser for peas cereal, dressings,	geno-toxic effects under realistic levels. with
	(172"Food additives permitted for direct addition to food for	ADI 0.2 mg/kg. NZ Food Regulations 1984, No
	human consumption, .135 lists permitted mg/kg limits in	271, list this material, for preparation of steam
	particular foods and uses for those foods - not dairy) E.g.	which can come in contact with food. This requires
	eyed peas, 500 mg/kg in strawberry pie, 0.1% in dry	technical grade. FSANZ FS Code 1.3.3.11 found
	non-nutritive sweeteners (21 CFR 180.37) USDA 9 CFR	for process & packaged water & subject to GMP.
	318.7 sufficient for purpose. ERMANZ Classification 6.1E	Purity wanted (per header & US FCC 7 (10-11) had Pb 10 Ha 1 ma/ka) Purity found (Unfound and
	Irritating to the eye 9.1C (fish) Harmful in the aquatic	may not be critical here).
Raw 6 Acid	environment NICNAS AICS found recorded as not assessed. ESANZ ES	FPA NZ (>10% Classification 6.1D (oral) Acutaly
	Code (1.3.3.3 processing aids GP with GMP. & 1.3.1	toxic 6.1E (dermal) Acutely toxic 8.1A Corrosive to
	schedule 1 cheese & kolas found, schedule 2 unfound).	metals 8.2C Corrosive to dermal tissue 8.3A
	USA FDA (21 GFR 182.1073 GRAS with GMP, USDA 9 CFR 318.7, 381 147 sufficient for purpose and limitation of	Lorrosive to ocular tissue 9.1D (other) Slightly harmful in the aquatic environment or are
	0.01% in lard shortening and poultry fat). Lewis toxicity	otherwise designed for biocidal action 9.3C
	data (Community-Right-To-Know List. EPA genetic	Harmful to terrestrial vertebrates). Side effects
	mg/m3, ACGIH TLV: TWA 1 mg/m3, STEL 3 mg/m3, ACGIH TLV: TWA 1 mg/m3, STEL 3 mg/m3	Efficacy: is per positive listing in IDF 9101 BS
	Human poison by unspecified route, moderately toxic by	5305. Purity wanted (per column header & US
	ingestion and skin contact. Corrosive agent to eyes, skin	FCC 7 (10-11) Pb 10, Hg 1 mg/kg & FSANZ also
L	and mucous memoranes, and a systemic poison by	I TEYUTE FUSZ, ASS I, MEAVY THEIDIS SAU THY/KY).

AsureQuality assessment by Global Proficiency for AsureQuality Ltd, ref H2136. Page 4 of a 7 page report + an extra cover letter page Ruakura Research Centre, Hamilton East, P O Box 20474 Hamilton, New Zealand 3241 Ph +64 7 850 4483, fax+64 7 850 4487, http://assessedproducts.asurequality.com/ Email:< bob.hutchinson@global-proficiency.com

	inhalation. A strong acid with neutralisation into food). LDL man 220 mg/kg, skin rabbit 595 mg/24hr severe, eye rabbit 119 mg severe.	Purity found (Unfound and may not be critical here).
Raw 7 Dye <0.5% likely trace	Unclassified w/o CAS etc Dye low-trace - low concern.	Purity wanted (per column header). Purity found: (Unfound and may not be critical here)
Raw 8 Dye <0.5% likely trace	Unclassified w/o CAS etc Dye low-trace - low concern.	Purity wanted (per column header). Purity found: (Unfound and may not be critical here)
Raw 9 ubiquitous	Ubiquitous & safe.	Purity wanted (per column header). Purity found: (Unfound and may not be critical here)
pH & micro status. Safe per sanitiser level note IDF 9101 alkalinity 0.02-0.5 , sequestrant 0.005-0.1, surfactant 0-0.05%, Chlorine 0.015-0.05%	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 enterolytica 4.4-9.6

Food-safety (per food listings FSANZ/ FDA 21 CFR/ Alimentary Standard slightly incomplete formulation here - and no
apparent raw material risk based on an approximate formulation in the SDS).

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

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

(Sofo 4) Sofo 4 Disinfactant	Begistrations column Scone: NZ shocks (NICNAS AICS	Durity column row purities to be per ESANZ purity
Cleaner H2136 30-04- 2018	Registrations column. Scope: N2 Checks (MICNAS AICS. 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	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	Instructions example (see table of use rates, use conditions,	SDS (Sections on identifiers for product &
summary & the extra table has concentrations & carryovers where pertinent	diseases & test results in the report table. http://www.safe4disinfectant/test results/safe 4 test results table.pdf - also DEFRA General Orders - Animal Diseases viz 10000x reduction of Salmonella cholerae suis NCTC10653 /5% yeast soil/4C/30 mins. DEFRA Diseases of Poultry & DEFRA Tuberculosis Order).	company, Hazards EC listings. labelling, contains Benzyl alkyldimethylammonium chloride, Alkylpolyethoxylate, & Ethylene diamine. Pictogram, Signal - Danger H318 causes serious eye damage, H315 causes skin irritation, EU H208 contains polyhexamethylene biguanide may cause allergic reaction. Composition with Ingredients with % range, CAS, EC No, REACH no, & hazard statements (Benzyl alkyl dimethyl ammonium chloride 3-5% hazards, Polyhexamethylene biguanide HCl <1%, Alkyl C9-11 polyethoxylate 3- 7%, Dipropylene glycol monomethyl ether 1-5%, EDTA 1-5%, Phosphoric acid <0.5%, Apple FAF229 <0.5%, Hexacol Blue/Green-7759 <0.5%, & Water >75%. Various SDS panel lists. Exposure controls (precautions plus Dipropylene glycol monomethyl ether TWA 308 mg/m3. Properties (pH 7-8 etc), Toxicology (similar to hazards with chronic values not classified). Ecology (is detailed). Transport (not-DG), Regulatory (Biodegradation complex with EC 648(2004 on datarapets)
		Complies with EC 648/2004 on detergents).
ACCP analysis of other aspects	Information and prior assessments (Renewed AsureQuality assessment see table of efficacy - http://www.safe4 disinfectant/test results/safe 4 test results table.pdf - also DEFRA General Orders - Animal Diseases viz 10000x reduction of Salmonella cholerae suis NCTC10653 /5% yeast soil/4C/30 mins. DEFRA Diseases of Poultry & DEFRA Tuberculosis Order HSR002530 cleaning products subsidiary hazard. All components on NZIoC). Food-safety (per food listings FSANZ/ FDA 21 CFR/ Alimentary Standard slightly incomplete formulation here - and no apparent raw material risk based on an approximate formulation in the SDS). QA, to ISO 9000 series and QC are not required for low contact here except raw IDs are mostly, not all, completed safe & QAC sanitiser present see safety table)	NZIOC listed ingredients etc Danger H318 causes serious eye damage, H315 causes skin irritation, EU H208 w/o product listing (?) Production side effects per low level indirect contact). Hygiene efficacy (is as above per table and website lab kill data in the word report)
Composition 100% carry over per farm model	All components listed or exempt EPA NZ NZIoC per HSNO Reg Section. Purities here may be more detailed than risk requires	Purity wanted (per column header). Purity found: (Unfound this time but previously white granules, Cl 55% pH 6-75 5-6 5, 20-60 mesh & moisture)
Benzalkonium chloride	NICNAS AICS Listings (found recorded "not assessed"?)	Lewis (Skin and eve irritant skin rabbit 1 mg/24H+
CAS 68424-85-1 50% from - , x -% is 3 - <5% Raw 1 Sanitiser QAC	NZIOC under group standard. EU Limit 0.5 mg/kg. Proposed 0.1 mg/kg which can apply to Milkpowder & implication of a 7x lower limit in milk may not now apply. FSANZ FS Code (Unfound/unscoped?). USA FDA (21 CFR 178.1010 found to 200 ppm as sanitisers of food contact surfaces, no excess, drained, and not necessarily rinsed or extended to dairys alkyl (C12-18) benzyldimethylammonium chloride compounds with mw 351-380, alkyl mainly C12-16 <1% C8- 10, may add ethanol or isopropanol, non-dairy & up 200 ppm in use solution & other countries which may require rinsing) antimicrobial agent in beets sugarcane, & regulated per FDA21CFR 18172.165 to 0.25 - 1.0 ppm), EU register (2032/2003 16(2). EPA (Classification 5-25% 6.1D (oral) Acutely toxic 6.5A (respiratory) Respiratory sensitisers 6.5B (contact) Contact sensitisers 6.9B (dermal) Harmful to human target organs or systems 8.2C Corrosive to dermal tissue 8.3A Corrosive to ocular tissue 9.1B (fish) Very ecotoxic in the aquatic environment 9.1B (algal) Very ecotoxic in the aquatic environment 9.3C Harmful to terrestrial vertebrates) ANZFA(no-n/a), EU register (2032/2003 16(2)).	eye rabbit 1mg.NEL was 0.25%+ (2500 ppm+) in a 2-year rat feeding trial (Alfredson BV 1951 "Toxicity studies on alkyldimethylbenzylammonium chloride in rats and dogs" J Am Pharm Assoc 40, 263-287) etc per Block "Antiseptics and disinfectants"). Side effects (ERMA scope, +IDF Bull 288 includes production also per food listings & Residue Reviews cheese effect at 5-20 mg/kg). Efficacy Block - (Antimicrobial profile mg/L E coli 200, Ps fluorescens 300, B subtilis 3, Fungi Aspergillus niger 60, C Globosum 10, M Verrucaria 40, L viridae 40, Algae Ch vularis 1, Stigeocloneum 0.7, Os Tenuis 0.6mg/L). Purity wanted (per column header). Purity found (Unfound and may not be critical here).
biguanide CAS 27083-27- 8 (cf 28757-47-3) 20%? X - % is <1% Raw 2 Antimicrobial	reviously unlisted. unavailable. NZIoC as a single component under a group standard: https:// www.federalregister. gov/articles/2008/01/09/E8-189/ "name" -exemption-from-the-requirement-of-a-tolerance. This includes milk tankers as an extreme test. It is also widely used on sutures (Figure 1) and in medical procedures with low toxicity: http://www. medscape. com/view article/561512_3. Australia/sanitiser for breweries/approved no specific regulations. NICNAS PECS no, & AICS found unassessed. Brazil/sanitiser for food handling equipment/	Norm Sea on - UK sector/data to Min of Energyin cat 2. USA/Preservation of silicones, tunnel pasteurisation waters,industrial/EPA Reg No 10182-128. Est reg no 10182-MA-01 notice 1989oil recovery systems/Amendment to ESA approval 1990. Toxicity: polyhexamethylene biguanide (CH2)3-NH-C(=NH)-NH-(CH2)3-)12.HCI is on the UK medicines act vet info service mavis list of defended substances 1997 re EU CR 434.97 extended MRL dead-line.It has an uncomplicated NOEL of 35+ mg/kg/day equivalent to equivalent to

AsureQuality assessment by Global Proficiency for AsureQuality Ltd, ref H2136. Page 6 of a 7 page report + an extra cover letter page Ruakura Research Centre, Hamilton East, P O Box 20474 Hamilton, New Zealand 3241 Ph +64 7 850 4483, fax+64 7 850 4487, http://assessedproducts.asurequality.com/ Email:< bob.hutchinson@global-proficiency.com

	October 1980, Reg No 1194 MOH - CISAD. Canada/sanitiser for food handling equipment/ June 1975, without rinse if used at 100 ppm or less. Denmark/sanitiser for food handling equipment/1977 May/J Official de le Republic Francaise no 1227 p 50. Germany/sanitiser for food handling equipment provided no residues remain. Allowed with rinse. No specific approval. New Zealand/sanitiser for dairy factories, for meat, game fish and poultry est./Dairy 1981 approved at 0.1% with rinse/other 1979, cleared with rinse. Sth Africa/disinfectant in breweries/approved no specific regs. Spain/sanitiser for food handling equipment/1977 Reg 37.8/M79 DG de Sanidad Trinidad/offshore use/Energy and Nat resources certain conditions, April 1983.	mrl 0.35 mg/kg/day and by comparison chlorhexidine toxicological ADI 0-0.005 mg/kg/day is per toxicity from degradation to chloraniline. Degradation components from PHMB appear related to of less concern (probably similar similar to food listed materials. Purity wanted (per column header). Purity found (Unfound and may not be critical here).
Alcohols C9-11 ethoxylated CAS 68439- 45-2 EPA HSR003338 from X-% is 3-7% Raw 3 on-ionic surfactant alkyl ethoxylate.	Similar has NICNAS AICS listed w/o concern. EPA NZ listed HSR00xxxx ok. USAFDA21CFR178.1010 - FOUND - similar to alpha lauryl-omega-hydroxypolyoxyethylene with an average 8-9 moles of ethylene oxide and an average molecular weight of 400. Per 21CFR178.1010 - for food and milk containers but not as a final rinse. Also similar to alpha alkyl – omega- hydroxypoly(oxyethylene) by condensation of C11-13 straight chain randomly substituted secondary alcohols with an average of 7-20 moles of ethylene oxide. For emulsifiers and or surface- active agents for articles for food manufacture. Also compare 21 CFR173.315.	FSANZ Food Standards Code 1.3.3.3 processing aids generally - FOUND.P Side effects are ok per BS5750 and IDF Bull 288 environmental listings. Efficacy is per BS 5750 and IDF 9101, & 9701 listings. Purity wanted (per column header inc FCC list). Purity found (Unfound and may not be critical here).
EPA HSR001402 from - x - % is 1-5% Raw 4 polyether	NICNAS AICS listed unassessed. EPA HSR00xxxx W/o exclusion. Similar material has FSANZ FS Code 1.3.3.3 similar listing & 21 CFR 178.1010 & similar 178.3400 etc bridging listings. Includes safe glycol dimer & methyl terminated & protected vs C2 stripping of terminal alkyl groups & likely significantly safer than solvent used as direct food ingredient e.g. in chewing gum.	(10-11) unfound). Purity found (Unfound and may not be critical here).
Tetrasodium EDTA CAS 64-02-8 86-88% from -, -% is 1-5% Raw 5 Sequestrant Phosphoric acid 85% CAS 7664-38-2 from - x -% is <0.5% Raw Raw 6 Acid	NICNAS AICS listed as not assessed. EPA NZ under HSR00xxxx. 21 CFR 173. 310 "secondary direct food substances permitted in food for human consumption"310 "boiler water additives not in excess and listed in the section). Also has registered uses as hog scald sequestrant and stabiliser for peas cereal, dressings, sausage, pies as regulated per 21CFR172.135 (172"Food additives permitted for direct addition to food for human consumption, .135 lists permitted mg/kg limits in particular foods and uses for those foods - not dairy) E.g. to 150 mg/kg in aqueous multivitamins, 145 mg/kg in black eyed peas, 500 mg/kg in strawberry pie, 0.1% in dry non-nutritive sweeteners (21 CFR 180.37)USDA 9 CFR 318.7 sufficient for purpose. ERMANZ Classification 6.1E (oral) Acutely toxic, 6.3B Mildly irritating to the skin, 6.4A Irritating to the eye 9.1C (fish) Harmful in the aquatic environment NICNAS AICS found recorded as not assessed. FSANZ FS Code (1.3.3.3 processing aids GP with GMP. & 1.3.1 schedule 1 cheese & kolas found, schedule 2 unfound). USA FDA (21 CFR 182.1073 GRAS with GMP, USDA 9 CFR 318.7, 381.147 sufficient for purpose and limitation of 0.01% in lard shortening and poultry fat). Lewis toxicity data	Poison by intravenous, moderately toxic by ingestion, experimental reproductive and mutagenic effects and toxicity data is available generally and ex BASF it is not absorbed, excreted inside 24 hours, with no carcinogenic, mutagenic, geno-toxic effects under realistic levels. with extended studies. The NOEL for NTA is 20 mg/kg, ADI 0.2 mg/kg. NZ Food Regulations 1984, No 271, list this material, for preparation of steam which can come in contact with food. This requires no entrained water, and that the additive is at least technical grade. FSANZ FS Code 1.3.3.11 found for process & packaged water & subject to GMP. Purity wanted (per header & US FCC 7 (10-11) had Pb 10, Hg 1 mg/kg). Purity found (Unfound and may not be critical here). EPA NZ (>10% Classification 6.1D (oral) Acutely toxic 6.1E (dermal) Acutely toxic 8.1A Corrosive to metals 8.2C Corrosive to dermal tissue 8.3A Corrosive to ocular tissue 9.1D (other) Slightly harmful in the aquatic environment or are otherwise designed for biocidal action 9.3C
	(Community-Right-To-Know List. EPA genetic toxicology program. OSHA-PEL; TWA 1 mg/m3, STEL 3 mg/m3, ACGIH TLV: TWA 1 mg/m3, STEL 3 mg/m3. Human poison by unspecified route, moderately toxic by ingestion and skin contact. Corrosive agent to eyes, skin and mucous membranes, and a systemic poison by inhalation. A strong acid with neutralisation into food). LDL man 220 mg/kg, skin rabbit 595 mg/24hr severe, eye rabbit 119 mg severe.	Harmful to terrestrial vertebrates). Side effects (ERMA and IDF Bull 288 not negatively listed). Efficacy: is per positive listing in IDF 9101, BS 5305. Purity wanted (per column header & US FCC 7 (10-11) Pb 10, Hg 1 mg/kg & FSANZ also require Pb<2, As<1, Heavy metals <40 mg/kg). Purity found (Unfound and may not be critical here).
Apple FAF229 CAS mixture hazards not classified Raw 7 Dye <0.5% likely trace	Unclassified w/o CAS etc Dye low-trace - low concern.	Purity wanted (per column header). Purity found: (Unfound and may not be critical here)
Hexacol Blue/ Green - 77590 CAS mixture hazards not classified Raw 8 Dye <0.5% likely trace	Unclassified w/o CAS etc Dye low-trace - low concern.	Purity wanted (per column header). Purity found: (Unfound and may not be critical here)
Water Raw 9 ubiquitous	Ubiquitous & safe.	Purity wanted (per column header). Purity found: (Unfound and may not be critical here)
pH & micro status. Safe per sanitiser level note IDF 9101 alkalinity 0.02-0.5 , sequestrant 0.005-0.1, surfactant 0-0.05%, Chlorine 0.015-0.05%	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 enterolytica 4.4-9.6

AsureQuality assessment by Global Proficiency for AsureQuality Ltd, ref H2136. Page 7 of a 7 page report + an extra cover letter page Ruakura Research Centre, Hamilton East, P O Box 20474 Hamilton, New Zealand 3241 Ph +64 7 850 4483, fax+64 7 850 4487, http://assessedproducts.asurequality.com/ Email:< bob.hutchinson@global-proficiency.com