19/08/2020 reference H4397

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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,

**Hand & Hygiene Sanitising Biodegradable Wet Wipes - Hand & Surface Wipes**

- Product description: hand and surface sanitiser (PHMB + QAC etc)
- Product use: hands and non-food contact surfaces

**"Passed AsureQuality assessment for food/ beverage/ dairy farm & factory hands and surfaces with up to incidental contact & any residue removed" H4397 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 hands and surfaces with up to incidental contact & any residue removed & stop if hand irritation occurs. Carry-over to food is minimised to ensure food function or composition are not affected, that residues are within applicable limits and that food legislation requirements are met.
- The assessment is subject to notification of change and expires on 19/08/2025.
- The full report is attached for supplier review and verification. The assessment is activated by countersigning & inclusion of assessment precautions / assessment statement / MPI dairy statement. (Efficacy per formula w/o lab biocidal test or wipecloth composition data)

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

Supplier:..... 19.08.20 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 - Checks (Food Std Australia-NZ, US FDA 21 CFR/ NSF, Food Chemicals Codex, NICNAS AICS, EPA NZ, EU, French culinary listings or related data for equivalent safety). Background (Aust Accord, 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:**

- Prior registrations (New AsureQuality Assessment).
- Food safety (is per hands/ surfaces incidental contact and ingredients from within food /safety list here). Purity (was not required or found for low levels and incidental contact here). Residue carryover to food (low ppb & << limits cited here (may be <1 millionth of levels here).
- QA (ISO 9000 series cert was not required or found),
- QC (Chemistry safety above and Micro safety is per sanitiser levels & not pH).
- Instructons – Label
    - Offshoot (NZ) Limited address Hand and Hygiene Sanitising BIODEGRADABLE Wet Wipes PURPOSE: Cleaning and Disinfectant Biodegradable Wet Wipes for both hands and surfaces. Wipes are effective against a wide range of micro-organisms and are gentle on hands. Ideal for fast, hygienic cleaning and are particularity suitable for areas where repeated sanitising is required, such as food preparation areas, gym's, supermarkets, sports facilities and shopping centres. Kills 99.9% of germs and bacteria that may cause illnesses. Use anytime, anywhere. Leaves hands refreshed without any residue and leaves a pleasant lemon scent. DIRECTIONS: To Open and use with the correct dispenser: 1. Slowly peel back label 2. Open dispenser and insert inside 3. Feed centre of wipes through dispensers until ready to use 4. Close dispenser to retain moisture 5. Pull out wipes as needed To Open and use WITHOUT a dispenser: 1. Slowly peel back label 2. Pull out wipes as needed Product Name: Hand and Hygiene Sanitising BIODEGRADBLE Wet Wipes Copyright© Offshoot (NZ) Ltd 3. Reseal to retain moisture For Hands: 1. Pull out Wet Wipe as needed 2. Use wipes to clean and sanitise hands ensuring both sides of hands are wet 3. Dispose of wipes in the trash or recycling 4. Let hands dry For Surfaces: 1. Remove excess dirt from surface and rinse food surfaces thoroughly with water before and after use 2. Pull out Wet Wipe as needed 3. Use wipes to sanitise surface and then rinse with clean water 4. Dispose of wipes in the trash or suitable company method. SAFETY PRECAUTIONS: Keep away from heat and flame. Do not drink or smoke while using. Stop use if causing irritation to skin. Dispose of empty container in a safe manner. Safe to use in food areas avoiding food contact. WARNING - Keep out of eyes and mouth. If a rash or other irritation occurs discontinue use). SDS (not sighted)
- Unwanted effects (OSH w/o SDS & table refers to NZIoC and Cosmetics lists. Production side effects by nil-vanishingly low contact).
- Efficacy (Is by claim & formula vs literature references and test data was not sighted at this stage)

**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).***

- Prior registrations (New AsureQuality Assessment).

**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**

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|---|---|---|
| (Offshoot NZ Ltd) Antibacterial Biodegradable Gym Wipes H4397 19-08-2020 | Registrations column. Scope: NZ checks (NICNAS AICS. FSANZ, US FDA 21 & 40 CFR/ NSF, Food Chemicals Codex, EPA NZ, EU, French culinary listings, WHO or MPI, 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 Scope: 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 Analysis vs Instructions summary. | Offshoot (NZ) Limited address Hand and Hygiene Sanitising BIODEGRADABLE Wet Wipes PURPOSE: Cleaning and Disinfectant Biodegradable Wet Wipes for both hands and surfaces. Wipes are effective against a wide range of micro-organisms and are gentle on hands. Ideal for fast, hygienic cleaning and are particularity suitable for areas where repeated sanitising is required, such as food preparation areas, gym’s, supermarkets, sports facilities and shopping centres. Kills 99.9% of germs and bacteria that may cause illnesses. Use anytime, anywhere. Leaves hands refreshed without any residue and leaves a pleasant lemon scent. DIRECTIONS: To Open and use with the correct dispenser: 1. Slowly peel back label 2. Open dispenser and insert inside 3. Feed centre of wipes through dispensers until ready to use 4. Close dispenser to retain moisture 5. Pull out wipes as needed To Open and use WITHOUT a dispenser: 1. Slowly peel back label 2. Pull out wipes as needed Product Name: Hand and Hygiene Sanitising BIODEGRADBLE Wet Wipes Copyright© Offshoot (NZ) Ltd 3. Reseal to retain moisture For Hands: 1. Pull out Wet Wipe as needed 2. Use wipes to clean and sanitise hands ensuring both sides of hands are wet 3. Dispose of wipes in the trash or recycling 4. Let hands dry For Surfaces: 1. Remove excess dirt | SDS (not sighted) |


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| HACCP analysis beyond instructions. | Prior registrations (New AsureQuality Assessment). Food safety (is per hands/ surfaces incidental contact and ingredients from within food /safety list here). Purity (was not required or found for low levels and incidental contact here). Residue carryover to food (low ppb & << limits cited here (may be <1 millionth of levels here). QA (ISO 9000 series cert was not required or found), QC (Chemistry safety above and Micro safety is per sanitiser levels & not pH) | Unwanted effects (OSH w/o SDS & table refers to NZIoC and Cosmetics lists. Production side effects by nil-vanishingly low contact). Efficacy (Is by claim & formula vs literature references and test data was not sighted at this stage) |
| Formulation combined 100% & advised supplied diluted100x. | We did not see density to allow this calculation | |
| Raw 1 moisturiser | EPA NZ Cosmetic list unreturned. AICS listed no 2nd notification. CTFA listed for skin applications. Aloe is a popular house plant due to its reputation as a healing plant for burns, cuts and other skin problems since ancient times. Aloe is mentioned in the New Testament at John 19:39-40 And there came also Nicodemus, which at the first came to Jesus by night, and brought a mixture of myrrh and aloes... Caution should be exercised before using Aloe from an Aloe plant because contact dermatitis can occur in sensitive individuals. You should cut away the skin and inner layer of yellow juice leaving only the actual gel. The yellow juice, especially prominent in older plants, is the primary irritant in the cases of contact dermatitis. | Test a small area of skin, such as the inner forearm, for a reaction before more general use. As with Aloe arborescens, ingestion of the latex, which is found just under the skin, can cause a cathartic (purging) reaction by irritating the large intestine. One of the components of Aloe is a compound called Aloin. It was a common ingredient in laxative products until the FDA banned its use in 2003. Aloin is now typically removed during processing. Purity wanted (per column header). Purity found (not required or found for near nil contact) |
| Raw 2 surfactant | Cosmetic standard unreturned on CAS. NICNAS AICS (returned human health tier 1 no 2nd notification required). NZIoC HSR00xxxx found. FSANZ Food Standards Code (1.3.3 Processing aids permits substances listed "generally" (includes food additives listed in schedule 2 of standard 1.3.1 found #1200 poly-dextroses, #1400 dextrins white and yellow, roasted starch, (ex microbial action on starch etc.), #460 cellulose, #461 methylcellulose, #464 hydroxypropylmethylcellulose, #465 methylethylcellulose. USA EPA 40 CFR 180.940 listed limit none. USAFDA21CFR172.841 polydextrose in baked goods etc and limited to 15g/serving. meth, antifoams, catalysts….11 permitted processing aids used in packaged water and in water used as an ingredient in other foods. CFR184.1277, 186.1275, as binder for baked goods GRAS with GMPUSAFDA21CFR1788.1010 sanitisers drained and not necessarily rinsed includes poly-ethers with short to long chain alkylation | Alkyl (C10-16) poly-glycosides; exemptions from the requirement for a tolerance EPA federal register…when used as an inert ingredient in or on growing crops, when applied to raw agricultural commodities after harvest or to animals - eliminates the need to establish a maximum permissible level for residues of ...(these). MSDS only found with a toxicity acute and carcinogenicity and teratogenicity not known (????). The surfactant used in Quantum XL is classified as free-rinsing due to its high HLB, thus it should be readily rinsed with cold water. HLB of APG 0810 is 15 – 16 as shown below. FIL attached surfactant physical properties & we also found a review that this class surfactant was free rinsing. Purity wanted per column header) Purity found (not required or found per non-incidental contact) |
| Raw 3 surfactant sanitiser | Not found on EPA NZ cosmetic prohibited & similar BZK compound returned <0.1% in non-rinse and 3% in hair rinsed. AICS returned with no 2nd notification. NZIoC HSR00xxxx returned. EU Limit 0.1 mg/kg which can apply to Milk powder & implication of a 7x lower limit in milk may not now apply. Similar chloride salt: USAFDA21CFR178.1010 (17) di n alkyl C8-10 dimethyl ammonium chlorides having average molecular weights of 332-361 and either ethanol or isopropanol. In addition to use on food processing equipment and utensils this solution may be used on food contact surfaces in public eating places. Solutions identified in b17 of this section shall provide when ready to use a level of 150 mg/kg of quaternary ammonium compound. FSANZ '2000 1.3.3 Processing aids - not quickly found but is BS5305 IDF 9101, 9701 listed. Side effects: inhibition of commercial fermentation at high levels (5+ mg/kg), and not a particular concern environmentally per 10 day life in streams, short streams, and refer IDF Bulletin 288, but note needs care since use is stopped for this reason in parts of Europe. | 40 CFR 180.940 to 240 ppm. Similar chloride salt ERMANZ HSR002708 UN Number UN Class Classification 3.1C Flammable Liquids: medium hazard 6.1C (oral) Acutely toxic 6.5B (contact) Contact sensitisers 8.2B Corrosive to dermal tissue 8.3A Corrosive to ocular tissue 9.1A (fish) Very eco-toxic in the aquatic environment 9.1A (crustacean) Very eco-toxic in the aquatic environment 9.1A (algal) Very eco-toxic in the aquatic environment 9.3B Eco-toxic to terrestrial vertebrates Purity wanted (per column header). Purity found (not required or found for near nil contact) |
| Raw 4 antimicrobial | EPA NZ cosmetic standard to 1%, under group standard w/o restriction. AICS human health tier 2 no 2nd notification required. Similar material has USAFDA21CFR178.1010 food contact surface sanitiser not necessarily rinsed or extended to dairy. ANZFA not found. Chemical study on alkylphenols (relates?) RKZ/2001.029 & note reports show feeding NOAEL 30+ mg/kg, & possible carcinogenicity & endocrine disruption mean an ADI is not set so approval is subject to reviews? | MICs maybe around 0.05% depending on base. Purity wanted (per column header). Purity found (not required or found per non-incidental contact) |
| Raw 5 surfactant sanitiser | EPA NZ cosmetics GP list CAS search of 4 unreturned, & 5 returned <0.1% in non-rinse and 3% in hair rinsed. NICNAS | Lewis (Skin and eye irritant skin rabbit 1 mg/24H+, eye rabbit 1mg.NEL was 0.25%+ (2500 ppm+) in a 2 year rat |


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| | AICS Listings returned human heath tier 2 & no 2nd notification. NZIoC under group standard. EU Limit 0.5 mg/kg. Proposed 0.1 mg/kg which can apply to Milk powder & implication of a 7x lower limit in milk may not now apply. FSANZ FS Code (Unfound/ un-scoped?). USA EPA 40 CFR 180.940 per structure not CAS total use solution 200 ppm. 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 dairy...s 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 (crustacean) 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)). | 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 (not found or required for non-incidental contact) |
| Raw 6 antimicrobial | NICNAS AICS listed. NZIoC returned as single component under appropriate group. EPA NZ Cosmetic Group Std List CAS unreturned & name max amount 0.3% www.federalregister. gov/articles/2008/01/09/E8-189/ phmb-exemption-from-the-requirement-of-a-tolerance. This includes milk tankers as an extreme test.<br>It is also widely used on sutures (Figure 1) and in medical procedures with low toxicity: http://www.medscape.com/viewarticle/561512_3. Australia/sanitiser for breweries/approved no specific regulations. NICNAS PECS no, & AICS found unassessed. Review on the efficacy, safety and clinical applications of polyhexanide, a modern wound antiseptic. Pubmed Hübner NO1, Kramer A. Cosmetic ingredient review stated insufficient evidence & also ref In 2017, the Scientific Committee on Consumer Safety (SCCS) issued a final opinion stating that the use of Polyaminopropyl Biguanide as a preservative in all cosmetic products at concentrations up to 0.1% is safe and that its use in sprayable formulations is not advised. 2 Brazil/sanitiser for food handling equipment/ 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. | UK North Sea oil - UK sector/data to Min of Energy.in cat 2. USA/Preservation of silicones, tunnel pasteurisation waters - industrial../EPA Reg No 10182-128. Est reg no 10182-MA-01 notice 1989....oil recovery systems/Amendment to ESA approval 1990. Toxicity: polyhexamethylenebiguanide (CH2)3-NH-C(=NH)-NH-(CH2)3-)12.HCl is on the UK medicines act vet info service mav is list of defended substances 1997 re EU CR 434.97 extended MRFL deadline. It has an uncomplicated NOEL of 35+ mg/kg/day equivalent to equivalent to 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 to food listed materials. Purity wanted (per column header). Purity supplied (not required or found for no-incidental contact) |
| Raw 7 fragrance | Advised fragrance trace w/o D-limonene and no concern (cf this was important as that had EPA NZ Cosmetics list < 0.001% non-rinsed & <0.01% rinsed. AICS wants 2nd notification. EPA NZ NZIoC HSR002725 Limonene & terpineol USFDA21CFR182.60 etc as direct flavour w/o excess, The IARC classifies d-limonene as a Group 3 carcinogen: not classifiable as to its carcinogenicity to humans. Recorded as irritant). | Purity wanted (per column header). Purity found (not required or found for near nil contact) |
| Raw 8 ubiquitous | Ubiquitous & safe | |
| Sum ingredients () vs 100% | | |
| control by antimicrobial as pH may be inside 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 enterolytica 4.4-9.6 |

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Food safety (is per hands/ surfaces incidental contact and ingredients from within food /safety list here). Purity (was not required or found for low levels and incidental contact here). Residue carryover to food (low ppb & << limits cited here (may be <1 millionth of levels here).

- **12 The formulation in confidence follows & is not for public circulation n/a in this case**


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| Formulation combined 100% & advised supplied diluted100x. | We did not see density to allow this calculation | |
| Aloe Barbadensis Leaf Extract 85507-69-3 from Ningbo Ninhua International Ltd 0.1% w/w Raw 1 | EPA NZ Cosmetic list unreturned. AICS listed no 2nd notification. CTFA listed for skin applications. Aloe is a popular house plant due to its reputation as a healing plant for burns, cuts and other skin problems since ancient times. Aloe is mentioned in the New Testament at John 19:39-40 And there came also Nicodemus, which at the first came to Jesus by night, and brought a mixture of myrrh and aloes... Caution should be exercised before using Aloe from an Aloe plant because contact dermatitis can occur in sensitive individuals. You should cut away the skin and inner layer of yellow juice leaving only the actual gel. The yellow juice, especially prominent in older plants, is the primary irritant in the cases of contact dermatitis. | Test a small area of skin, such as the inner forearm, for a reaction before more general use. As with Aloe arborescens, ingestion of the latex, which is found just under the skin, can cause a cathartic (purging) reaction by irritating the large intestine. One of the components of Aloe is a compound called Aloin. It was a common ingredient in laxative products until the FDA banned its use in 2003. Aloin is now typically removed during processing. Purity wanted (per column header). Purity found (not required or found for near nil contact) |
| Decyl Glucoside 58846-77-8 from Ningbo Ninhua International Ltd 0.06% w/w Raw 2 surfactant | Cosmetic standard unreturned on CAS. NICNAS AICS (returned human health tier 1 no 2nd notification required). NZIoC HSR00xxxx found. FSANZ Food Standards Code (1.3.3 Processing aids permits substances listed "generally" (includes food additives listed in schedule 2 of standard 1.3.1 found #1200 poly-dextroses, #1400 dextrins white and yellow, roasted starch, (ex microbial action on starch etc.), #460 cellulose, #461 methylcellulose, #464 hydroxypropylmethylcellulose, #465 methylethylcellulose. USA EPA 40 CFR 180.940 listed limit none. USAFDA21CFR172.841 polydextrose in baked goods etc and limited to 15g/serving. meth, antifoams, catalysts….11 permitted processing aids used in packaged water and in | Alkyl (C10-16) poly-glycosides; exemptions from the requirement for a tolerance EPA federal register…when used as an inert ingredient in or on growing crops, when applied to raw agricultural commodities after harvest or to animals - eliminates the need to establish a maximum permissible level for residues of ...(these). MSDS only found with a toxicity acute and carcinogenicity and teratogenicity not known (????). The surfactant used in Quantum XL is classified as free-rinsing due to its high HLB, thus it should be readily rinsed with cold water. HLB of APG 0810 is 15 – 16 as shown below. FIL attached surfactant physical properties & we also found a review that this class surfactant was free rinsing. Purity wanted |


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| | water used as an ingredient in other foods. CFR184.1277, 186.1275, as binder for baked goods GRAS with GMPUSAFDA21CFR1788.1010 sanitisers drained and not necessarily rinsed includes poly-ethers with short to long chain alkylation | per column header) Purity found (not required or found per non-incidental contact) |
| Didecyldimethylammonium chloride 7173-51-5 from Ningbo Ninhua International Ltd 0.3% Raw 3 surfactant sanitiser | Not found on EPA NZ cosmetic prohibited & similar BZK compound returned <0.1% in non-rinse and 3% in hair rinsed. AICS returned with no 2nd notification. NZIoC HSR00xxxx returned. EU Limit 0.1 mg/kg which can apply to Milk powder & implication of a 7x lower limit in milk may not now apply. Similar chloride salt: USAFDA21CFR178.1010 (17) di n alkyl C8-10 dimethyl ammonium chlorides having average molecular weights of 332-361 and either ethanol or isopropanol. In addition to use on food processing equipment and utensils this solution may be used on food contact surfaces in public eating places. Solutions identified in b17 of this section shall provide when ready to use a level of 150 mg/kg of quaternary ammonium compound. FSANZ '2000 1.3.3 Processing aids - not quickly found but is BS5305 IDF 9101, 9701 listed. Side effects: inhibition of commercial fermentation at high levels (5+ mg/kg), and not a particular concern environmentally per 10 day life in streams, short streams, and refer IDF Bulletin 288, but note needs care since use is stopped for this reason in parts of Europe. | 40 CFR 180.940 to 240 ppm. Similar chloride salt ERMANZ HSR002708 UN Number UN Class Classification 3.1C Flammable Liquids: medium hazard 6.1C (oral) Acutely toxic 6.5B (contact) Contact sensitisers 8.2B Corrosive to dermal tissue 8.3A Corrosive to ocular tissue 9.1A (fish) Very eco-toxic in the aquatic environment 9.1A (crustacean) Very eco-toxic in the aquatic environment 9.1A (algal) Very eco-toxic in the aquatic environment 9.3B Eco-toxic to terrestrial vertebrates Purity wanted (per column header). Purity found (not required or found for near nil contact) |
| Phenoxyethanol 122-99-6 from Ningbo Ninhua International Ltd 0.08% Raw 4 antimicrobial | EPA NZ cosmetic standard to 1%, under group standard w/o restriction. AICS human health tier 2 no 2nd notification required. Similar material has USAFDA21CFR178.1010 food contact surface sanitiser not necessarily rinsed or extended to dairy. ANZFA not found. Chemical study on alkylphenols (relates?) RKZ/2001.029 & note reports show feeding NOAEL 30+ mg/kg, & possible carcinogenicity & endocrine disruption mean an ADI is not set so approval is subject to reviews? | MICs maybe around 0.05% depending on base. Purity wanted (per column header). Purity found (not required or found per non-incidental contact) |
| Benzalkonium Chloride 68424-85-1 from Ningbo Ninhua International Ltd 0.08% Raw 5 surfactant sanitiser | EPA NZ cosmetics GP list CAS search of 4 unreturned, & 5 returned <0.1% in non-rinse and 3% in hair rinsed. NICNAS AICS Listings returned human heath tier 2 & no 2nd notification. NZIoC under group standard. EU Limit 0.5 mg/kg. Proposed 0.1 mg/kg which can apply to Milk powder & implication of a 7x lower limit in milk may not now apply. FSANZ FS Code (Unfound/ un-scoped?). USA EPA 40 CFR 180.940 per structure not CAS total use solution 200 ppm. 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 dairy...s 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 (crustacean) 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)). | Lewis (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 (not found or required for non-incidental contact) |
| Polyhexamethylene Biguanide 32289-58-0 27083-27-8 from Ningbo Ninhua International Ltd 0.06% Raw 6 antimicrobial | NICNAS AICS listed. NZIoC returned as single component under appropriate group. EPA NZ Cosmetic Group Std List CAS unreturned & name max amount 0.3% www.federalregister. gov/articles/2008/01/09/E8-189/ phmb-exemption-from-the-requirement-of-a-tolerance. This includes milk tankers as an extreme test.<br>It is also widely used on sutures (Figure 1) and in medical procedures with low toxicity: http://www.medscape.com/viewarticle/561512_3. Australia/sanitiser for breweries/approved no specific regulations. NICNAS PECS no, & AICS found unassessed. Review on the efficacy, safety and clinical applications of polihexanide, a modern wound antiseptic. Pubmed Hübner NO1, Kramer A. Cosmetic ingredient review stated insufficient evidence & also ref In 2017, the Scientific Committee on Consumer Safety (SCCS) issued a final opinion stating that the use of Polyaminopropyl Biguanide as a preservative in all cosmetic products at concentrations up to 0.1% is safe and that its use in sprayable formulations is not advised. 2 Brazil/sanitiser for food handling equipment/ October 1980, Reg No 1194 MOH - CISAD. Canada/sanitiser for food handling equipment/ June 1975, without rinse if used at 100 | UK North Sea oil - UK sector/data to Min of Energy.in cat 2. USA/Preservation of silicones, tunnel pasteurisation waters - industrial../EPA Reg No 10182-128. Est reg no 10182-MA-01 notice 1989....oil recovery systems/Amendment to ESA approval 1990. Toxicity: polyhexamethylenebiguanide (CH2)3-NH-C(=NH)-NH-(CH2)3-)12.HCl is on the UK medicines act vet info service mav is list of defended substances 1997 re EU CR 434.97 extended mrl deadline. It has an uncomplicated NOEL of 35+ mg/kg/day equivalent to equivalent to 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 to food listed materials. Purity wanted (per column header). Purity found (not required or found for near nil contact) |


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| | 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. | |
| Lemon oil from Ningbo Ninhua International Ltd 0.3% w/w Raw 7 fragrance | Advised fragrance trace w/o D-limonene and no concern (cf this was important as that had EPA NZ Cosmetics list < 0.001% non-rinsed& <0.01% rinsed. AICS wants 2nd notification. EPA NZ NZIoC HSR002725 Limonene & terpineol USFDA21CFR182.60 etc as direct flavour w/o excess, The IARC classifies d-limonene as a Group 3 carcinogen: not classifiable as to its carcinogenicity to humans. Recorded as irritant). | Purity wanted (per column header). Purity found (not required or found for near nil contact) |
| Water CAS 7732-18-5 from from Ningbo Ninhua International Ltd made to 100% Raw 8 ubiquitous | Ubiquitous & safe | |
| Sum ingredients () vs 100% | | |
| control by antimicrobial as pH may be inside 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 enterolytica 4.4-9.6 |

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19/08/2020 reference H4397

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Dear Wesley Binedell,

Please find attached your assessment report for any questions or suggestions and the invoice and later the web listing should follow soon. I hope it is as you intended or please advise.

**Hand & Hygiene Sanitising Biodegradable Wet Wipes - Hand & Surface Wipes**

- Product description: hand and surface sanitiser (PHMB + QAC etc)
- Product use: hands and non-food contact surfaces
- Status: passed new AsureQuality assessment $NZ340 + GST for 2 hours. I hope this is as you intended or please advise.

**"Passed AsureQuality assessment for food/ beverage/ dairy farm & factory hands and surfaces with up to incidental contact & any residue removed" H4397 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 hands and surfaces with up to incidental contact & any residue removed & stop if hand irritation occurs. Carry-over to food is minimised to ensure food function or composition are not affected, that residues are within applicable limits and that food legislation requirements are met.
- The assessment is subject to notification of change and expires on 19/08/2025.
- The full report is attached for supplier review and verification. The assessment is activated by countersigning & inclusion of assessment precautions / assessment statement / MPI dairy statement. (Efficacy per formula w/o lab biocidal test or wipe-cloth composition data)

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


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