

13/10/2020 reference H4424

Gold Rock Limited (importer) Address (physical & postal): 2/7 Proteus Place, Half Moon Bay, Auckland 2012. Phone: 0221692296 Fax: Contact: 0221692296 Contact Syed Termizi syed@goldrock.co.nz. Manufacturer Shanghai Jian & Mei Industry and Trade Co, Ltd

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,

Nano Silver

- Product description: nano silver solution
- Product use: for hand and hard surface disinfection

"Passed AsureQuality assessment for food / beverage / dairy factory hands and hard surfaces with food contact surface residues drained & minimised e.g. safe water rinsed to dry" H4424 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 hard surfaces with food contact surface residues drained & minimised e.g. safe water rinsed to dry. 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 12/10/2025.
- 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.

Prepared by Global Proficiency for AsureQuality Ltd... *R J Hutchinson*

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 and prior assessments (Passed new AsureQuality food/ beverage dairy assessment pending sanitiser efficacy data. MPI 6/10/2020 MPI Approved C42 non-dairy animal products with food contact surfaces drained before return of product, packaging and process operations).
- Food safety (per instructed indirect contact use & ingredients found in food/ safety listing group above. Extra data on Ag & Ag+ levels possible). Purities (sighted vs China standards similar to Food Chem Codex & FSANZ in table header). Residue carryover (is per low hand contact or drain & rinse below 1/5000 use rate c.f. EPA USA).
- QA (ISO 9000 unreturned low risk).
- QC (finished product testing including micro safety by efficacy test).
- Instructions –
 - Label (JM NANO. Nano Silver. Rinse Free. Disinfectant. Lasts up to 96 hours on hands. Long lasting on had surfaces. Kills 99.99% of germs. Nano Silver Antibacterial Hand Sanitiser & Disinfectant. History and advantage list and "easy applicability & highly effective antibacterial, antiviral and antifungal properties shown to kill 650 kinds of bacteria. Ingredients deionised water, silver ions 50 ppm. Application (use spray device to evenly spray from 20cm & let dry normally without cleaning or wiping). Precautions (Avoid drinking. External use only. Not for medical use. Keep out of reach of children. Use with caution if sensitive to Silver. Avoid sunljght & store cool & dry. May have yellow brown precipitate after long storage. After using this compound food contact surfaces must be thoroughly rinsed with potable water before production starts. JM Nano. Nano Silver. Rinse Free. Disinfectant. Lasts up to 96 hours on hands. Long lasting on hard surfaces. Kills 99.99% of germs. Properties & suitability listed. Imported and distributed by Gold Rock etc details & manufactured by Shanghai Jian & Mei details).
 - MSDS (Nano Silver Solution for disinfection per manufacturer address. Hazards – non-harmful. Composition water CAS 7732-18-5 99.8%, & Silver ion CAS 7440-22-4 (silver as such) 0.2% w/w. Lists. Exposure controls listed and no limits available. Properties listed. Lists. Toxicology listed. Regulatory listed (understood not EPANZ classified)
- Unwanted effects (MSDS & NZIoC & CCID have Hazard data. Production side effects are inferred only per food listing of oxidised material & non-irritation in test). Irritancy test - Multiple skin irritation test report 14/04/2020 on NZ rabbits sighted concluded it was non-irritant.
- Hygiene efficacy (there is standard food industry antibacterial test organism data passed with over 5 log reduction at 0.5-1.5 minutes as

well as virus reduction information summarised in the table below & here. Per GB 15979-2002 appendix B Total bacterial colonies <20/<200 cfu/ml, Total fungal colonies <20/<100 Coliforms ND/ND. Staph aureus ND/ND, Ps aeruginosa ND/ND, Haemolytic organisms ND/ND. Technical Standard for disinfection MOH 2002 & 3% tween 80 neutraliser. 2.1.1.7 - E coli ATCC 8739 kill log >6.40/5 limit (1/2 min, similarly 1 min and 1.5 minutes)- Staph aureus ATCC 6538 kill >6.26/5 limit (1/2 min, similarly 1 & 1.5 min). Candida albicans ATCC 10231 >6.25/5 (1/2 min, similarly 1 & 1.5 min)

- o Similarly Gmicro testing results for flu virus >99.99% etc.
- o Similarly Guang Zhou Institute of microbiology report KY20200083 nanosilver solution 30 ppm for Shanghai Jian & Mei Industry 17/02/2020 Killing Test (Coronaviridae HcoV0229E >99.99% reduction).

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
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 inc "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 (Sitll completing passed newASUREQuality food/ beverage dairy assessment pending sanitiser efficacy data & no other registrations were sighted).

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

(Gold Rock - Shanghai Jian & Mei) Nano Silver H4424 13-10-2020	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 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	Label (JM NANO. Nano Silver. Rinse Free. Disinfectant. Lasts up to 96 hours on hands. Long lasting on had surfaces. Kills 99.99% of germs. Nano Silver Antibacterial Hand Sanitiser & Disinfectant. History and advantage list and "easy applicability & highly effective antibacterial, antiviral and antifungal properties shown to kill 650 kinds of bacteria. Ingredients deionised water, silver ions 50 ppm. Application (use spray device to evenly spray from 20cm & let dry normally without cleaning or wiping). Precautions (Avoid drinking.	MSDS (Nano Silver Solution for disinfection per manufacturer address. Hazards – non-harmful. Composition water CAS 7732-18-5 99.8%, & Silver ion CAS 7440-22-4 (silver as such) 0.2% w/w. Lists. Exposure controls listed and no limits available. Properties listed. Lists. Toxicology listed. Regulatory listed (understood not EPANZ classified))

	External use only. Not for medical use. Keep out of reach of children. Use with caution if sensitive to Silver. Avoid sunlight & store cool & dry. May have yellow brown precipitate after long storage. After using this compound food contact surfaces must be thoroughly rinsed with potable water before production starts. JM Nano. Nano Silver. Rinse Free. Disinfectant. Lasts up to 96 hours on hands. Long lasting on hard surfaces. Kills 99.99% of germs. Properties & suitability listed. Imported and distributed by Gold Rock etc details & manufactured by Shanghai Jian & Mei details).	
Efficacy tests (& also added irritancy test)	Per GB 15979-2002 appendix B Total bacterial colonies <20/<200 cfu/ml, Total fungal colonies <20/<100 Coliforms ND/ND. Staph aureus ND/ND, Ps aeruginosa ND/ND, Haemolytic organisms ND/ND. Technical Standard for disinfection MOH 2002 & 3% tween 80 neutraliser. - section 2.1.1.7 - E coli ATCC 8739 kill log >6.40/5 limit (1/2 min, similarly 1 min and 1.5 minutes). Staph aureus ATCC 6538 kill >6.26/5 limit (1/2 min, similarly 1 & 1.5 min). Candida albicans ATCC 10231 >6.25/5 (1/2 min, similarly 1 & 1.5 min).	Similarly Gmicro testing results for flu virus >99.99% etc. Similarly Guang Zhou Institute of microbiology report KY20200083 nanosilver solution 30 ppm for Shanghai Jian & Mei Industry 17/02/2020 Killing Test (Coronaviridae HcoV0229E >99.99% reduction). Irritancy test - Multiple skin irritation test report 14/04/2020 on NZ rabbits sighted concluded it was non-irritant
HACCP analysis of other aspects	Information and prior assessments (Passed new AsureQuality food/ beverage dairy assessment pending sanitiser efficacy data. MPI 6/10/2020 MPI Approved C42 non-dairy animal products with food contact surfaces drained before return of product, packaging and process operations). Food safety (per instructed indirect contact use & ingredients found in food/ safety listing group above. Extra data on Ag & Ag+ levels possible). Purities (sighted vs China standards similar to Food Chem Codex & FSANZ in table header). Residue carryover (is per low hand contact or drain & rinse below 1/5000 use rate c.f. EPA USA). QA (ISO 9000 unreturned low risk). QC (finished product testing including micro safety by efficacy test)	Unwanted effects (MSDS & NZIoC & CCID have Hazard data. Production side effects are inferred only per food listing of oxidised material & non-irritation in test). Hygiene efficacy (there is standard food industry antibacterial test organism data passed with over 5 log reduction at 0.5-1.5 minutes as well as virus reduction information summarised in the table below)
Composition total 100% Carryover is per farm dairy model Purity C of A of finished product made from ingredients below	Guangdong Institute of Analysis China National Analytical Centre Guangzhou 18/03/2020 test report. Reported against Safety & technical standards for cosmetics 2015. Nano Silver deionised water Silver 50.3 mg/kg Pb <0.5/<10 ppm limit, As <0.1/<2 mg/kg limit, Hg <0.1/<1 mg/kg limit. Stability 54C/14 days lost 1.4%=<10. Ph value 10.21.	Pony Testing International Group. 31/03/2020 J Mnano Nano Silver Antibacterial Spray Substances of very high concern per European Chemicals Agency ECHA – according to analytical results concentrations of 205 SVHC are less than 0.1% in the submitted sample.
Raw 1 ubiquitous Raw 2 sanitiser	Ubiquitous & safe Safety data NZIoC HSR003077 & CCID 9.1All, F, G & A all re Ecotoxicology. Safety is cross-referenced below & Silver TGA C177820 oral solution must not exceed 0.3% Silver and other products not more than 1% Silver data private & unavailable to this case. Literature search for efficacy (unreturned and wants data to be submitted to complete this – we noted numerous progress w/o completed efficacy data. Wikipedia (reports mechanism but no active levels - to irreversibly damage key enzyme systems in the cell membranes of pathogens)	Silver and most silver compounds have an oligodynamic effect and are toxic for bacteria, algae, and fungi in vitro. The antibacterial action of silver is dependent on the silver ion.[11] The effectiveness of silver compounds as an antiseptic is based on the ability of the biologically active silver ion. There is an FDA warning on claims (Ag p Purity wanted (per column header & FCC). Purity found (unfound)
Related material safety Silver nitrate CAS 7761-88-8	EPA40CFR180.940 Ag+ not Ag for FCS to 50 ppm. EPANZ eye lash/brow to 4 ppm & use with restriction. EPA NZ HSNO HSR00 5.1.1B, 6.3A, 6.9B (All), 6.9B (O), 8.3A, 9.1A (All), 9.1A (F), 9.1A (C), 9.1A (A), 9.1A (Oth), 9.2B, 9.3B. Silver NZDWS MAV is rated unnecessary /unlikely/ non-hazardous. USEPA NAAS 0.05 mg/L as ambient water quality & effective per USEPA 1980. FSANZ 1.3.3.11 to 0.01 mg/kg in process/bottled water. NICNAS listed ok not assessed. Other information (1) the average dose in drinking water is 0.004 mg/L compared with authorized Silver levels in drinking water (2) USA, Canada, Russia, Japan 0.05 mg/L, (3) EU 0.08 mg/L, and (4) Switzerland 0.1 mg/L.	FSANZ Food Standards Code'2000 1.3.3.11 "permitted processing aids used in packaged water and in water used as an ingredient in other foods" - has Silver ions 0.01 mg/kg. Side effects: unexpected below defaults etc. Efficacy: is according to test data. Purity wanted (per column header FSANZ and FCC latter unfound). Purity see for completed formulation as noted for raw 1 above)
Other related material safety Silver oxide, Ag2O, CAS 20667-12-3	NZIoC HSR001346. HSNO Hazard Classifications - 5.1.1B, 6.1D (All), 6.1D (O), 9.1A (All), 9.1A (F), 9.1A (C), 9.3C. Based original application Silver data the Silver level may be 0.012-0.014 mg/L but may exceed the NZDWS limit of 0.02 mg/L. WHO guidelines 2003 for drinking water quality state that where silver salts are used to maintain bacterial quality of drinking-water levels of Silver up to 0.1 mg/L can be tolerated without risk to health. EPA USA National Drinking Water Regs give a 2ndary limit of 0.1 mg/L Jennings www.watertechonline. WHO says 0.1 mg/L for bacteriology leads to 10g intake in 70 year lifetime their NOAEL.	Purity see for completed formulation as noted for raw 1 above
Total needs clarification of raw 2		

GP HD pH margins of 2 & 12.5 and IDF guide alkalinity 0.02-0.6%, surfactant 0.001-0.1%, Chlorine 0% or 0.015-0.025%)	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
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- Food safety ((per instructed indirect contact use & ingredients found in food/ safety listing group above but need clarification of Ag & Ag+ levels together). Purities (requested but not found). Residue carryover (is per low hand contact or drain & rinse below 1/5000 use rate c.f. EPA USA).
- **12 The formulation in confidence follows & is not for public circulation**

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Water CAS 7732-18-5 from - 99.5% or 99.995% Raw 1 ubiquitous	Ubiquitous & safe	
Nano Silver CAS 7440-22-4 50 ppm by purity C of A test above (not 0.05 g/ml, or 0.2% or 0.005 g/ml) Raw 2 santiser	Safety data NZIoC HSR003077 & CCID 9.1AII, F, G & A all re Ecotoxicology. Safety is cross-referenced below & Silver TGA C177820 oral solution must not exceed 0.3% Silver and other products not more than 1% Silver data private & unavailable to this case. Literature search for efficacy (unreturned and wants data to be submitted to complete this – we noted numerous progress w/o completed efficacy data. Wikipedia (reports mechanism but no active levels - to irreversibly damage key enzyme systems in the cell membranes of pathogens)	Silver and most silver compounds have an oligodynamic effect and are toxic for bacteria, algae, and fungi in vitro. The antibacterial action of silver is dependent on the silver ion.[11] The effectiveness of silver compounds as an antiseptic is based on the ability of the biologically active silver ion. There is an FDA warning on claims (Ag p Purity wanted (per column header & FCC). Purity found (unfound)
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Gold Rock Limited (importer) Address (physical & postal): 2/7 Proteus Place, Half Moon Bay, Auckland 2012. Phone: 0221692296 Fax: Contact: 0221692296 Contact Syed Termizi syed@goldrock.co.nz Manufacturer Shanghai Jian & Mei Industry and Trade Co, Ltd

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

Dear Syed Termizi,

Sayed thanks for payment this is a covering letter to please find attached your assessment report for any questions or suggestions & the web listing should follow.

Nano Silver

- Product description: nano silver solution
- Product use: for hand and hard surface disinfection
- Status - Passed AsureQuality Assessment \$365.5 + GST for 2:15 hours and thanks for data held in confidence. Original report 12/10 re-reported 13/10/2020

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