

12/03/2018 reference H3023

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To whom it may concern,

SAN-AIR Gel

- Product description: air purifier made from essential oils
- Product use: for with portable air treatment

"Passed AsureQuality assessment for food/ beverage/ dairy factory air treatment with no food contact" H3023 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-OSHenvironment approval (& previously AQIS).

Conditions:

- Used per instructions, legislation, & GMP, as air treatment with no food contact or taint.
- Carry-over to food should be avoided.
- The assessment is subject to notification of change and expires on 12/03/2023.
- The full report is attached for supplier review and verification. The assessment is activated by countersigning.
- Lab efficacy sighted/ available.

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



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:

- Prior registrations (AsureQuality Assessment renewed. HSNO reporting criteria not met).
- Food safety (is by non-contact plus Kilford original safety opinion).
- QA (ISO 9000 series certification etc n/a for non-contact).
- QC (Per QA above and micro safety is by preservative levels here & lab test data for antimicrobial effect & pH may lie in microorganism growth ranges).

- Instructions
 - SAN-AIR Gel label (Remove foil before use. Contains 100 g SAN-AIR Gel blend of Australian essential oils. Warning is food safe but avoid contact & wash hands with soap and water. Use away from children and eating).
 - San-Air Label (For use in indoor air space vs mildew & musty odours Remover foil & replace cap and set opening to suit cupboards or air conditioning. Keep away from children. If contacted wash with soap & water. Allergy sufferers caution. Contains essential oils & natural bonding agents).
 - SDS (Hazardous per ASCC criteria, & Not Dangerous per ADG code, Risk phrases not hazardous - no criteria found, Safety phrases S25 avoid contact with eyes. Potential health effects (Inhalation short term data not harmful & unlikely discomfort or irritation, long term no data. Skin similarly. Eye contact may be mildly irritating short term & no data long term. Ingestion unlikely may be mild discomfort short term and no long-term data. No carcinogen listing by ASCC, NTP or IARC. Toxicology no data on particular target organs). Original Safety opinion (Kilford & Kilford Pty Ltd Clean Air Gel.you..list.. 17 fragrant ingredients & i& indicative concentrations of each. All of the fragrant ingredients are well known & frequently used in industrial fragrances and should not offer any significant hazards to workers who may contact it. However as it is a fragrance with 20-50% fragrant ingredients it should not be allowed to come in direct contact with food as to do so would impart its fragrance (and some flavour) to the food).
- Unwanted effects (Covered by instructions in label (& SDS wanted) & Kilford safety opinion Production side effects ok non-contact to avoid flavour or odour effects) .
- Efficacy (Field efficacy sighted approximate summary so please refer to originals. Manufacturer Blossom labs refers to independent test reports AMS 0606604 bactericidal efficacy, AMS 1710795/1, 2 for sporicidal and fungicidal efficacy. Mixture of micrococcus luteus, Staph capitis and Staph hominis at showed 55.5% reduction/ 30 minutes/ with record of product loss to air. Bactericidal effects for E-coli, Ps aeruginosa and S aureus had time/ loss values 28.7% in 30 mins, 83.1% in 60 mins and 99% in 120 minutes - TGA 54 schedule 2 vs E coli, S aureus, Listeria monocytogenes & Micrococcus luteus and 76.4-99.9% loss at 5 min and 95-99% in 30 minutes).

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 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 (AsureQuality Assessment renewed. HSNO reporting criteria not met).

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

<p>San-Air Australia - SAN-AIR Gel H3952 12-03-2018 Formula belongs to San-Air only</p>	<p>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</p>	<p>Purity column raw purities to be per FSANZ purity wanted (as ingredient etc) FCC7 2010-2011 with GMP indicators & FSANZ also (require Pb<2, As<1, Heavy metals <40 mg/kg). Purity column.</p>
<p>HACCP vs Instruction summary & the extra table has concentrations & carryovers where pertinent</p>	<p>SAN-AIR Gel label (Remove foil before use. Contains 100 g SAN-AIR Gel blend of Australian essential oils. Warning is food safe but avoid contact & wash hands with soap and water. Use away from children and eating). San-Air (For use in indoor air space vs mildew & musty odours Remove foil & replace cap and set opening to suit cupboards or air conditioning. Keep away from children. If contacted wash with soap & water. Allergy sufferers caution. Contains essential oils & natural bonding agents. . SDS (Hazardous per ASCC criteria, & Not Dangerous per ADG code, Risk phrases not hazardous - no criteria found, Safety phrases S25 avoid contact with eyes. Potential health effects (Inhalation short term data not harmful & unlikely discomfort or irritation, long term no data. Skin similarly. Eye contact may be mildly irritating short term & no data long term. Ingestion unlikely may be mild discomfort short term and no longterm data. No carcinogen listing by ASCC, NTP or IARC. Toxicology no data on particular target organs).</p>	<p>Original Safety opinion (Kilford & Kilford Pty Ltd Clean Air Gel..you..list.. 17 fragrant ingredients & i& indicative concentrations of each. All of the fragrant ingredients are well known & frequently used in industrial fragrances and should not offer any significant hazards to workers who may contact it. However as it is a fragrance with 20-50% fragrant ingredients it should not be allowed to come in direct contact with food as to do so would impart its fragrance (and some flavour) to the food).</p>
<p>HACCP checklist applied to total formulation.</p>	<p>Prior registrations (AsureQuality Assessment renewed. HSNO reporting criteria not met). Food safety (is by noncontact plus Kilford original safety opinion). QA (ISO 9000 series certification etc n/a for non-contact). QC (Per QA above and micro safety is by preservative levels here</p>	<p>Unwanted effects (Covered by instructions in label (& SDS wanted) & Kilford safety opinion Production side effects ok non-contact to avoid flavour or odour effects) . Efficacy (Field efficacy sighted approximate summary so please refer to originals. Manufacturer</p>

	& lab test data for antimicrobial effect & pH may lie in microorganism growth ranges).	Blossom labs refers to independent test reports AMS 0606604 bactericidal efficacy, AMS 1710795/1, 2 for sporicidal and fungicidal efficacy. Mixture of micrococcus luteus, Staph capitis and Staph hominis at showed 55.5% reduction/ 30 minutes/ with record of product loss to air. Bactericidal effects for E-coli, Ps aeruginosa and S aureus had time/ loss values 28.7% in 30 mins, 83.1% in 60 mins and 99% in 120 minutes - TGA 54 schedule 2 vs E coli, S aureus, Listeria monocytogenes & Micrococcus luteus and 76.4-99.9% loss at 5 min and 95-99% in 30 minutes).
Composition 100% carry over per farm model (factory overestimate)	Question of components listed or exempt EPA NZ NZIoC per HSNO Reg Section.	
Raw 1 essential oil	NZIoC unlisted. AICS unfound. Food listings unfound. Oral, dermal & inhalation toxicity undetermined per thegoodscentco etc. Cosmetic & fragrance not for flavour use. IFA guidance on essential oils unfound re carcinogenicity, toxicity, phototoxicity, methyleugenol effects list, found on irritation list, & not found on allergens list. Food Chem Toxicol. 2006 May;44(5):616-25. Epub 2005 Oct 21. A review of the toxicity of Melaleuca alternifolia (tea tree) oil. Hammer KA1, Carson CF, Riley TV, Nielsen JB. Author information Abstract The essential oil of Melaleuca alternifolia, also known as tea tree or melaleuca oil, is widely available and has been investigated as an alternative antimicrobial, antiinflammatory and anti-cancer agent. While these properties are increasingly well characterised, relatively limited data are available on the safety and toxicity of the oil.	Food Chem. Toxicol. 2006 Anecdotal evidence from almost 80 years of use suggests that the topical use of the oil is relatively safe, and that adverse events are minor, self-limiting and occasional. Published data indicate that neat oil is toxic if ingested in higher doses and can also cause skin irritation at higher concentrations. Allergic reactions to neat oil occur in predisposed individuals and may be due to the various oxidation products that are formed by exposure of the oil to light and/or air. Adverse reactions may be minimised by avoiding ingestion, applying only diluted oil topically and using oil that has been stored correctly. Data from individual components suggest that neat oil has the potential to be developmentally toxic if ingested at higher doses, however, neat oil and its components are not genotoxic. The limited ecotoxicity data available indicate that neat oil is toxic to some insect species but more studies are required. PMID: 16243420 DOI: 10.1016/j.fct.2005.09.001 [Indexed for MEDLINE] Purity wanted (per column header). Purity found (n/a for non-contact)
Raw 2 essential oil	NZIoC HSR00xxxx sighted ok.. AICS unfound Google..FDA PART 182 -- SUBSTANCES GENERALLY RECOGNIZED AS SAFE Sub-part A--General Provisions IFA guidance on essential oils unfound re carcinogenicity, toxicity, phototoxicity, methyleugenol effects list, irritation list, & allergens list.	Essential Oils in Food Preservation, Flavor and Safety 2016, Pages 501–508. https://doi.org/10.1016/B978-0-12-416641-7.00057-2 Get rights and content Abstract popular aromatic plants native to the Mediterranean region. Aqueous extracts, essential oils, and dried parts of these plants have long been used in cosmetics, hygiene products, and traditional medicines. In addition, they are used as food additives due to their pleasant flavor and aroma, and their antibacterial, antifungal, insect repellent, insecticidal, and antioxidant properties. With increasing concerns about loss of effectiveness and safety of commercial antibiotics, antifungals, insecticides, and preservatives, botanical products, included, are coming to the forefront. In this review, the current and potential applications of these essential oils in the food sciences are discussed. EO Essential oil GABA Gammaaminobutyric acid Purity wanted (per column header). Purity found (n/a for non-contact)

Raw 3 essential oil	NZIoC & AICS would need CAS search. Main active found 21CFR172.515 as a flavouring agent various uses not in excess. Wikipedia - used by indigenous Australians - young aromatic leaves to treat colds, headaches and general sickness [34] The steam distilled leaf oil of the cineole chemotype is also used externally for coughs, colds, neuralgia, and rheumatism.[35] A nerolidol and linalool chemotype is also cultivated and distilled on a small scale for use in perfumery.	Purity wanted (per column header). Purity found (n/a for non-contact)
Raw 4 gelling agent	NZIoC HSRooxxxx found w/o restriction. AICS list 1, assess1, site 0 2nd assessment 0. unfound. USAFDA21CFR 173 etc listed for various food uses, similarly FSANZ as direct ingredient.	Purity wanted (per column header). Purity found (n/a for non contact)
Water to 100% ubiquitous	Ubiquitous and safe	
pH within micro growth range & control per antimicrobial effect of concentrate	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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