

04/12/2013 Reference H1773

Global Proficiency Ltd for AsureQuality Ltd,
Ruakura Research Centre, Hamilton East,
P O Box 20474 Hamilton.

CRC Industries Ltd, 10 Highbrook Drive East Tamaki Auckland
Phone 09 272 2700, fax 09 2749696. Contact John Sokolich
email sokolichj@crc.co.nz

To whom it may concern,

Food Grade Silicone

- Which is: lubricant
- For: food areas, incidental contact

"Passed AsureQuality assessment for food/beverage/dairy factory incidental contact" H1773 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: use per instructions of a minimum quantity as release agent, lubricant with potential exposure, & protective film - latter washed or wiped to prevent transfer). Dairy transfer low e.g. <1% x values for 21CFR food limits of hydrocarbon <10 mg/kg, silicone here <1 mg/kg &..... as permitted not prohibited see references.

General conditions:

- The product is to be used according to Manufacturer's Instructions (reflecting the assessment etc), Good Manufacturing Practice (GMP), and applicable legislation.
- Usage and carry-over to food should be minimised to ensure food function or composition are not affected, that residues are within applicable Maximum Residue Limits (MRLs/MAVs), and that food legislation requirements are met..
- The assessment is subject to notification of change (e.g. in formulation, raw materials or instructions) and expires on 03/12/2018.
- The full report is attached for supplier review and verification. The assessment is activated by countersigning.

Prepared by Global Proficiency for AsureQuality Ltd...



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:

- Food safety per tabled usage within listed permissions.
- QA, QC (unrequired for incidental contact here).
- Instructions (Label, bulletin & MSDS sighted consistent at original assessment).
- Side effects (not expected for incidental contact at permitted food levels/ or less for eg dairy).
- Efficacy: lubrication does not impact food safety

Contents

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

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).

- Response/status: information is fair.

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

(CRC) Food Grade Silicone H1773 03-12-2013	Registrations column. 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	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.
	Food safety per tabled usage within listed permissions. QA, QC (unrequired for incidental contact here). Instructions (Label, bulletin & MSDS sighted consistent at original assessment)	Side effects (not expected for incidental contact at permitted food levels/ or less for eg dairy)
Raw 1 Silicone	FOUND SIMILAR FDA21CFR178.3570 listed for incidental contact from equipment etc. to food with all residues minimised and food residue specifically limited to 1 ppm max. FOUND SIMILAR FSANZ Food Standards Code 2000 unfound except as antifoam with GMP	Quality Manual, Approval System Procedures
Raw 2 propellant	FSANZ FS Code (1.3.3 Miscellaneous additives permitted in accordance with GMP in processed foods specified in the schedule & this cross-credits to processing aids). USA FDA (21CFR174.1655 GRAS with GMP for purpose of aerating agent, gas, propellant used variously).	Toxicity (OSHA PEL TWA 1000 ppm, etc. Flammable gas label flammable gas. Safety central nervous system effects at high concentrations. An asphyxiant flammable gas etc).
Potential micro challenge with pH growth ranges	pH growth ranges: B cereus 4.4-9.3, Campylobacter jejuni 4.9-9.0, C botulinum A & B 4.8-8.5 type E 5-8.5, C perfringens 5-8.9, Listeria monocytogenes 4.5-8.0, Salmonella 3.8-9,	Staph aureus 4.3-9.0, vibrio cholerae 6-11, vibrio parahaemolyticus 4.8-9, vibrio vulnificus 5-10, Yersinia enterocolitica 4.4-9.6

- Food safety per tabled usage within listed permissions.
-

Raw materials should be suitable- e.g. sanitisers for sanitising etc

- Raw materials comply per food safety listings/data for similar use in section 1 & refer to unwanted effects in section 6.

3 Standard:

Additives are to be manufactured consistently safe - per quality assurance to ISO 9002 (& labs should be certified to ISO Guide 25). Detergent and Sanitisers should be listed with the Code of Practice Group (see manufacturers parent code).

- QA, QC (unrequired for incidental contact here).

4 Standard:

Formulation quality control - continues 3 above.

Raw materials should be controlled at manufacturers stated levels (+/- 5% x level and this can be covered by quality assurance but the manufacturer will have make/QC sheets..). Purity: The target should be taken from the raw materials standards in Food Chemicals Codex (Arsenic, Heavy metals and Foreign Matter).

- QA, QC (unrequired for incidental contact here).

Quality assurance of use

5 Label: to provide for quality assurance of use; trace-ability and description including mode of use (per ref 6 method 3.5 a) to be complete and clear (c.f. farms check list below).

- **Label instructions are to provide quality assurance of the method of use for efficacy, safety and side effects by addressing key points:**
- **Product name •, batch •, expiry • etc**
- **Distributors/Manufacturers name and address •**
- **The description of the substance e.g. detergent/ sanitizer/ detergent-sanitiser, general purpose/ heavy duty detergent, nature of sanitizer active, level of foaming (low, medium and high), routine or periodic treatment, and compatibility to levels of hardness. (These can be similar to Australian Standards & AQIS). •**
- **The description of the type of equipment to be treated •**
- **The use instructions concentration, temperature in and out, time/and typical volumes. All the steps in the cleaning routine, the hot temperatures at incoming and dump, permitted cold steps, the acid and alkali routine, and reference to periodic cleaning. They include safe residue minimisation (drainage, & rinse before next milking or air purge etc).**
- **Warnings about possible harmful effects and the other regulatory etc requirements should be met but may be outside the food safety scope.**
- **Note NZ may use e.g. 10L/cluster, enough solution for re-circulation, 75C initial solutions (or to not damage & dump the pipeline machine at 65C and BMT at >55C).**
- **Instructions (Label, bulletin & MSDS sighted consistent at original assessment).**

Performance

6 Standard:

To be free from apparent side effects: inc taint, corrosion, inhibition, insolubility, market, or other effects.

- Side effects (not expected for incidental contact at permitted food levels/ or less for eg dairy).

7 Standard: Efficacy:

Efficacy: for detergents to clean and sanitisers to sanitise - to complete their part in sanitation systems to minimum food safety standards - and to industry established safety margins according to the particular product/process. This uses laboratory methods. Or it uses product outturn microbiological performance, as well as plant visual or microbiological status.

- Efficacy: lubrication does not impact food safety

8 Standard: containers/transport to be safe

- Response/status: is accepted according to the history of care.

9 Attachments:

- Roll over of unchanged data.

10 Standards are listed in the introduction and concentration table and references may be attached to the assessment file.

11 Contacts

- Bob E J Hutchinson PhD, Marion Buckley-Smith PhD for chemicals & otherwise n/a for Australia.

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

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	Food safety per tabled usage within listed permissions. QA, QC (unrequired for incidental contact here). Instructions (Label, bulletin & MSDS sighted consistent at original assessment)	Side effects (not expected for incidental contact at permitted food levels/ or less for eg dairy)
Silicone fluid SF18-350, polydimethylsiloxane fluid ex GE Silicones 5% Raw 1 Silicone	FOUND SIMILAR FDA21CFR178.3570 listed for incidental contact from equipment etc. to food with all residues minimised and food residue specifically limited to 1 ppm max. FOUND SIMILAR FSANZ Food Standards Code 2000 unfound except as antifoam with GMP	Quality Manual, Approval System Procedures
LPG liquefied petroleum gas CAS68476-85-7 Raw 2 paraffinic hydrocarbon	FSANZ FS Code (1.3.3 Miscellaneous additives permitted in accordance with GMP in processed foods specified in the schedule & this cross-credits to processing aids). USA FDA (21CFR174.1655 GRAS with GMP for purpose of aerating agent, gas, propellant used variously).	Toxicity (OSHA PEL TWA 1000 ppm, etc. Flammable gas label flammable gas. Safety central nervous system effects at high concentrations. An asphyxiant flammable gas etc).
Potential micro challenge with pH growth ranges	pH growth ranges: B cereus 4.4-9.3, Campylobacter jejuni 4.9-9.0, C botulinum A & B 4.8-8.5 type E 5-8.5, C perfringens 5-8.9, Listeria monocytogenes 4.5-8.0, Salmonella 3.8-9,	Staph aureus 4.3-9.0, vibrio cholerae 6-11, vibrio parahaemolyticus 4.8-9, vibrio vulnificus 5-10, Yersinia enterocolitica 4.4-9.6

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email sokolichj@crc.co.nz

Dear John Sokolich,

Please find attached your assessment report per unchanged data and updated format. Please let us know any questions or corrections and the invoice and web listing will follow.

Food Grade Silicone

- Which is: lubricant
- For: food areas, incidental contact
- Status: assessment factory renewed \$100 + GST, purity cross-credited

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