

05/10/2017 H2932

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& Ruakura Research Centre, Hamilton East,
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To whom it may concern,

Silicone Mist Aerosol

- Product description: lubricant oil
- Product use: food areas with incidental contact (H1)

"Passed AsureQuality assessment for food/beverage/dairy factory incidental contact" H2932 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 incidental food contact (release agent/ lubricant/ protective film as appropriate) minimum quantity/ transfer, washed or wiped. Dairy transfer low e.g. <1% of 21CFR178.3570 values of hydrocarbon <10 mg/kg, silicone here <1 mg/kg.
- The assessment is subject to notification of change and expires on 05/10/2022.
- The full report is attached for supplier review and verification. The assessment is activated by countersigning.

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

Supplier: *[Signature]* Date: *05/10/17*

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 status & prior registrations (Renewed New AsureQuality Assessment for incidental contact. NSF 147361 18/01/2013 for incidental contact H1 found.
- Food safety (raw material FSANZ & 21CFR & NSF listings in table. Purity for silicone found previously and propellant unfound & low risk). QA (n/a per incidental contact).
- QC specs (Chemical food safety is per raw materials as above. Micro safety is per manufacture condition & anhydrous formula).
- Instructions –
 - Label (Previous similar product "Hi-Performance Multilube Gel. Synthetic non-drip lubricant 500 ml, odourless & clear, does not attract dust, fresh & salt water proof, heat & pressure proof, does not drip off. Description - applied as a clear oil with excellent capillary action CRC Multilube penetrates quickly before solvents evaporate leaving a waterproof load bearing gel that stays in place and with stands high pressure & shock. Further description of applications etc. NZFSA approved C15 all animal products except dairy (means per machine directions of minimum quantity etc.). Directions shake can, spray light even coating, use extension tube for hard to reach places, and use minimum necessary & remove excess with clean cloth. HSNO information is detailed).
 - SDS (CRC (NZ) 3048 Silicone Mist. Hazard classification #s & phrases, hazard pictograms, GHS H222 extremely flammable aerosol, H303 may be harmful if swallowed, H333 or inhaled, H336 may cause drowsiness or dizziness. Composition Dimethyl, phenylmethylsiloxane, trimethyl terminated AS 63148-52-7 1-10%, Propane 30-60%, Butane 30-60%. Exposure controls Butane 1900 mg/m3 TWA. & some emergency limit values. . Toxicology per hazards & chronic data no hazard flags. Ecology listed. Transport requirements listed. Regulatory managed under HSR002515 flammable aerosols or other uses are n/a here. Raw materials listed Dimethyl, phenylmethylsiloxane, trimethyl terminated AS 63148-52-7 on NZIoC, Propane on IATA & NZIoC, Butane on IATA A& NZIoC. Lists for location, approved handler & tracking completed)
- Side effects (Environment/OSH are per SDS & NZIoC etc. Production side effects per food safety listings & non-contact, & caution flammable).
- Hygiene efficacy (Lubrication is un-related to this)

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 (higher post heat treatment)
Severity	Low	Low
Total	Low	Low (higher post heat treatment)

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 status & prior registrations (Renewed New AsureQuality Assessment for incidental contact. NSF 147361 18/01/2013 for incidental contact H1 found.

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 Industries) Silicone Mist Aerosol H2932 05-10-2017	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 & exception reporting	Formulation 100% Label (Previous similar product "Hi-Performance Multilube Gel. Synthetic non-drip lubricant 500 ml, odourless & clear, does not attract dust, fresh & salt water proof, heat & pressure proof, does not drip off. Description - applied as a clear oil with excellent capillary action CRC Multilube penetrates quickly before solvents evaporate leaving a waterproof load bearing gel that stays in place and with stands high pressure & shock. Further description of applications etc. NZFSA approved C15 all animal products except dairy (means per machine directions of minimum quantity etc.). Directions shake can, spray light even coating, use extension tube for hard to reach places, and use minimum necessary & remove excess with clean cloth. HSNO information is detailed).	SDS (CRC (NZ) 3048 Silicone Mist. Hazard classification #s & phrases, hazard pictograms, GHS H222 extremely flammable aerosol, H303 may be harmful if swallowed, H333 or inhaled, H336 may cause drowsiness or dizziness. Composition Dimethyl, phenylmethylsiloxane, trimethyl terminated AS 63148-52-7 1-10%, Propane 30-60%, Butane 30-60%. Exposure controls Butane 1900 mg/m3 TWA. & some emergency limit values. . Toxicology per hazards & chronic data no hazard flags. Ecology listed. Transport requirements listed. Regulatory managed under HSR002515 flammable aerosols or other uses are n/a here. Raw materials listed Dimethyl, phenylmethylsiloxane, trimethyl terminated AS 63148-52-7 on NZIoC, Propane on IATA & NZIoC, Butane on IATA A& NZIoC. Lists for location, approved handler & tracking completed)
HACCP analysis of other aspects	Information status & prior registrations (Renewed New AsureQuality Assessment for incidental contact. NSF 147361 18/01/2013 for incidental contact H1 found. Food safety (raw material FSANZ & 21CFR & NSF listings in table. Purity for silicone found previously and propellant unfound & low risk). QA (n/a per incidental contact). QC specs (Chemical food safety is per raw materials as above. Micro safety is per manufacture condition & anhydrous formula).	Side effects (Environment/OSH are per SDS & NZIoC etc. Production side effects per food safety listings & non-contact, & caution flammable) Hygiene efficacy (Lubrication is un-related to this)
Formulation 100% made up of components listed below & FCS contact carryovers per farm model in table		
Raw 1 Propellant HC	NZIoC had HSNO HSR# ok. Found in FDA21CFR174.1655 GRAS with GMP for purpose of aerating agent, gas, propellant used variously, OSHA PEL TWA 1000 ppm, etc. Flammable gas label	Purity wanted in column header & inferred for low/incidental contact. Micro ok per manufacturing conditions.

	flammable gas. Safety central nervous system effects at high concentrations. An asphyxiant flammable gas etc. FSANZ 1.3.3.9 Lubricants - not found. FSANZ 1.3.3 Processing aids also allows food additives in accordance with GMP in processed foods specified in the schedule...	
Raw 2 Propellant HC	NZIoC corrected CAS had HSR# ok Propellant similar to raw 5	Propellant similar to raw 6
Raw 3 Silicone	NZIoC HSR# ok. FSANZ-FSANZ as antifoam to residue level 10 mg/kg in food. FSANZ permitted lubricants, release & anti-sticks - not found. USA FDA 21 CFR 178.3570 - addition of silicone to food does not exceed 1 mg/kg defoaming agent per USA FDA 21 CFR 173.340 limitation of 10 mg/kg in food, or at such a level in a concentrated food that when prepared as directed on the labels, the food in its ready for consumption state will not have more than 10 mg/kg except as follows: zero in milk, 110 mg/kg in dry gelatine dessert mixes labelled for use whereby no more than 16 mg/kg is present in the ready to serve desert, 250 mg/kg in salt labelled for cooking whereby no more than 10 mg/kg is present in cooked food. ANZFA as antifoam to residue level 10 mg/kg in food. ANZFA permitted lubricants, release & anti-sticks - not found.	Antifoam and range of use appear to include FDA 21 CFR 173.340, 175.300, 176.210, 175.105, 176.170, 178.3120, 177.1210, 121.1099, 121.2514, 121.2519, 121.2520, 212,2525, 212.2534, and 121.2550. Purity wanted (dimethylpolysiloxane substantially free from hydrolysable chloride and alkoxy groups, no more than 18% loss in weight after heating 4 hours at 200 C, viscosity 300-1050 centistrokes at 25 C, RI 1.400-1.404 at 25 C). Purity found (from same supplier previously fluid food grade viscosity 350 cs)
Micro safety per manufacture conditions & while anhydrous	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 (raw material FSANZ & 21CFR & NSF listings in table. Purity for silicone found previously and propellant unfound & low risk).

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

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Formulation 100% made up of components listed below & FCS contact carryovers per farm model in table		
Propane CAS 74-98-6 HSNO HSR001010. from Greenstone Energy 46% Raw 1 Propellant HC	NZIoC had HSNO HSR# ok. Found in FDA21CFR174.1655 GRAS with GMP for purpose of aerating agent, gas, propellant used variously, OSHA PEL TWA 1000 ppm, etc. Flammable gas label flammable gas. Safety central nervous system effects at high concentrations. An asphyxiant flammable gas etc. FSANZ 1.3.3.9 Lubricants - not found. FSANZ 1.3.3 Processing aids also allows food additives in 1.3.3.sched 2 (Miscellaneous additives permitted in accordance with GMP in processed foods specified in the schedule...	Purity wanted in column header & inferred for low/incidental contact. Micro ok per manufacturing conditions.
Butane CAS 109-97-6 HSR000989 from Greenstone Energy 46% Raw 2 Propellant HC	NZIoC corrected CAS had HSR# ok Propellant similar to raw 5	Propellant similar to raw 6
Silicone Fluid 1000 cst Polydimethylsiloxane CAS 63148-62-0 NZIoC HSF003036. from Dow Corning 8% previously Silicone DC200/350 Food Grade from Dow Corning 8% Raw 3 Silicone	NZIoC HSR# ok. FSANZ-FSANZ as antifoam to residue level 10 mg/kg in food. FSANZ permitted lubricants, release & anti-sticks - not found. USA FDA 21 CFR 178.3570 - addition of silicone to food does not exceed 1 mg/kg defoaming agent per USA FDA 21 CFR 173.340 limitation of 10 mg/kg in food, or at such a level in a concentrated food that when prepared as directed on the labels, the food in its ready for consumption state will not have more than 10 mg/kg except as follows: zero in milk, 110 mg/kg in dry gelatine dessert mixes labelled for use whereby no more than 16 mg/kg is present in the ready to serve desert, 250 mg/kg in salt labelled for cooking whereby no more than 10 mg/kg is present in cooked food. ANZFA as antifoam to residue level 10 mg/kg in food. ANZFA permitted lubricants, release & anti-sticks - not found.	Antifoam and range of use appear to include FDA 21 CFR 173.340, 175.300, 176.210, 175.105, 176.170, 178.3120, 177.1210, 121.1099, 121.2514, 121.2519, 121.2520, 212.2525, 212.2534, and 121.2550. Purity wanted (dimethylpolysiloxane substantially free from hydrolysable chloride and alkoxy groups, no more than 18% loss in weight after heating 4 hours at 200 C, viscosity 300-1050 centistokes at 25 C, RI 1.400-1.404 at 25 C). Purity found (from same supplier previously fluid food grade viscosity 350 cs)
Micro safety per manufacture conditions & while anhydrous	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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