

19/06/2018 H3994

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To whom it may concern,


Ambersil Non Silicone Release FG

- Product description: release agent
- Product use: food areas as mould release agent M1

"Passed AsureQuality assessment for food/beverage/dairy factory mould release contact" H3994 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 mould release contact with a minimum quantity/ transfer (compare <21CFR178.3570 values of hydrocarbon <10 mg/kg, silicone here <1 mg/kg).
- The assessment is subject to notification of change and expires on 19/06/2023.
- 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:

- Information status & prior registrations (NSF Non-food programs listed M1 registration 149689. New AsureQuality Assessment. Labelled for MPI non-dairy animal product approved C15, & C81).
- Food safety (Raw materials food listed in 21CFR/ FSANZ Food Code/ Alimentary list/ equivalent safety data. Purity unfound low risk & cross-credit NSF registration).
- QA (n/a per low / incidental contact).
- QC specs (Chemical food safety is per raw materials as above. Micro safety is per manufacture condition & anhydrous formula).
- Instructions –
 - Label (Ambersil. Non- Silicone release FG Food Processing Safe (NSF Non-food programs listed M1 registration 149689. Release agent for food packaging. AsureQuality approved Passed AsureQuality Assessment MPI approved C15, & C81 - all animal products except dairy. Company contacts. "Non-staining release agent for use in manufacture of plastic items refer to TDS before first use. Danger extremely flammable aerosol. Pressurised container. May burst if heated. Causes skin irritation. May cause drowsiness or dizziness. Toxic to aquatic life with long lasting effects. Keep out of reach of children. Keep away from heat., hot surfaces, sparks, open flames & other ignition sources. No smoking. Do not spray on flame or ignition source. Do not pierce or burn even after use. Avoid breathing mist, vapours, spray. Use only outdoors or in well ventilated area. Protect from sunlight. Do not expose to temperatures exceeding 50C/122F. Dispose of contents / container in an authorised waste collection point. Contains hydrocarbons C6 Iso-alkanes, <5% n-Hexane.
 - TDS (Non-Silicone Release FG is a NSF M1 & H1 registered, non-silicone mould release agent. Based on 'edible' vegetable oils and has been formulated for the release of many commonly used types of polymers in the food processing industry. APPLICATIONS Provides a 'wet' non-silicone release film for the release of polymers utilised in injection moulding, vacuum forming and many other moulding and forming processes. Ideal for use in the production of food quality packaging. Will not build up in the mould and helps to improve surface finish, reduce rejects and increase production. Spray a light, even coating from 9" - 12" (25 - 30 cm) and re-apply as necessary). SDS (Says to read before use). Side effects (Environment/OSH are per SDS & RM listings on NZIoC & AICS & instructions re hazards.
- Production side effects per food safety listings & low contact and 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)

| | |
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| 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) |

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).

- Information status & prior registrations (NSF Non-food programs listed M1 registration 149689. New AsureQuality Assessment. Labelled for MPI non-dairy animal product approved C15, & C81).

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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| (CRC Industries) Ambersil Non-Silicone Release FG H3994 19-06-2018 | 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 | Label (Ambersil. Non- Silicone release FG Food Processing Safe (NSF Non-food programs listed M1 registration 149689. Release agent for food packaging. AsureQuality approved Passed AsureQuality Assessment MPI approved C15, & C81 - all animal products except dairy. Company contacts. "Non-staining release agent for use in manufacture of plastic items refer to TDS before first use. Danger extremely flammable aerosol. Pressurised container. May burst if heated. Causes skin irritation. May cause drowsiness or dizziness. Toxic to aquatic life with long lasting effects. Keep out of reach of children. Keep away from heat., hot surfaces, sparks, open flames & other ignition sources. No smoking. Do not spray on flame or ignition source. Do not pierce or burn even after use. Avoid breathing mist, vapours, spray. Use only outdoors or in well ventilated area. Protect from sunlight. Do not expose to temperatures exceeding 50C/122F. Dispose of contents / container in an authorised waste collection point. Contains hydrocarbons C6 Iso-alkanes, <5% n-Hexane. | TDS (Non-Silicone Release FG is a NSF M1 & H1 registered, non-silicone mould release agent. Based on 'edible' vegetable oils and has been formulated for the release of many commonly used types of polymers in the food processing industry. APPLICATIONS Provides a 'wet' non-silicone release film for the release of polymers utilised in injection moulding, vacuum forming and many other moulding and forming processes. Ideal for use in the production of food quality packaging. Will not build up in the mould and helps to improve surface finish, reduce rejects and increase production. Spray a light, even coating from 9" - 12" (25 - 30 cm) and re-apply as necessary). SDS (Says to read before use). |

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| HACCP analysis of other aspects | Information status & prior registrations (NSF Non-food programs listed M1 registration 149689. New AsureQuality Assessment. Labelled for MPI non-dairy animal product approved C15, & C81). Food safety (Raw materials food listed in 21CFR/ FSANZ Food Code/ Alimentary list/ equivalent safety data. Purity unfound low risk & cross-credit NSF registration). QA (n/a per low / 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 & RM listings on NZIoC & AICS & instructions re hazards. Production side effects per food safety listings & low contact and caution flammable). Hygiene efficacy (Lubrication is un-related to this) |
| Formulation 100% made up of components listed below | | |
| Raw 1 Natural oil | NZIoC HSR00xxxx recovered. AICS human health tier 1 no 2nd notification. This oil is one of the oldest vegetable oils, but historically was used in limited quantities due to high levels of erucic acid, which is damaging to cardiac muscle of animals, and glucosinolates, which made it less nutritious in animal feed.[24] Rapeseed oil can contain up to 54% erucic acid.[25] Food-grade canola oil derived from rapeseed cultivars, also known as rapeseed 00 oil, low erucic acid rapeseed oil, LEAR oil, and rapeseed canola-equivalent oil, has been generally recognized as safe by the United States Food and Drug Administration.[26] Canola oil is limited by government regulation to a maximum of 2% erucic acid by weight in the USA[26] and 5% in the EU,[27] with special regulations for infant food. These low levels of erucic acid are not believed to cause harm in human neonates.[26][27] In 1981, a deadly outbreak of disease in Spain, known as toxic oil syndrome,[28] was caused by the consumption of colza oil (a cousin of rapeseed oil procured from a similar species of B. rapa) for industrial use that was fraudulently sold as olive oil to be consumed in cooking, salads, and other foods. Symptoms appeared as a typical pneumonia with interstitial infiltrates on chest X-ray, complicated by pulmonary hypertension in a significant number of cases.[29] | Rapeseed pollen contains known allergens.[30][31] Whether rape pollen causes hay fever has not been well established, because rape is an insect-pollinated (entomophilous) crop, whereas hay fever is usually caused by wind-pollinated plants. The inhalation of oilseed rape dust may cause asthma in agricultural workers.[32] Purity wanted (per header & FCC). Purity found (low risk / cross-credit NSF) |
| Raw 2 Solvent | NZIoC HSR00xxxx returned. AICS returned no 2nd notification. FDA21CFR173.270 25 ppm in spice oleoresins, 2.2% in hops extracts, OSHA PEL TWA 50 ppm etc. Volatile and even incidental residue <0 ppb FSANZ 1.3.3.3 white mineral oil. FSANZ 1.3.1 & 1.3.3.13 lower alkanes permitted propellant and extraction agents | Purity wanted (per header & FCC). Purity found (low risk / cross-credit NSF) |
| Raw 3 Propellant HC | 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 1.3.1 & 1.3.3.13 lower alkanes permitted propellant and extraction agents FSANZ 1.3.3 Miscellaneous additives permitted in accordance with GMP in processed foods specified in the schedule & this cross-credits to processing aids. | Purity wanted (per header & FCC). Purity found (low risk / cross-credit NSF, 3rd component trace low risk) |
| Micro safety per heat treated production and anhydrous vs growth. | 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 materials food listed in 21CFR/ FSANZ Food Code/ Alimentary list/ equivalent safety data. Purity unfound low risk & cross-credit NSF registration).
- **12 The formulation in confidence follows & is not for public circulation**

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| (CRC Industries) Ambersil Non- Silicone Release FG H3994 19-06-2018 | 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. |
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| Formulation 100% made up of components listed below | | |
| Rapeseed oil CAS 8002-13-9 HSR003146 HSR003146 from Southern Lubricants 8% Raw 1 Natural oil | NZIoC HSR00xxxx recovered. AICS human health tier 1 no 2nd notification. This oil is one of the oldest vegetable oils, but historically was used in limited quantities due to high levels of erucic acid, which is damaging to cardiac muscle of animals, and glucosinolates, which made it less nutritious in animal feed.[24] Rapeseed oil can contain up to 54% erucic acid.[25] Food-grade canola oil derived from rapeseed cultivars, also known as rapeseed 00 oil, low erucic acid rapeseed oil, LEAR oil, and rapeseed canola-equivalent oil, has been generally recognized as safe by the United States Food and Drug Administration.[26] Canola oil is limited by government regulation to a maximum of 2% erucic acid by weight in the USA[26] and 5% in the EU,[27] with special regulations for infant food. These low levels of erucic acid are not believed to cause harm in human neonates.[26][27] In 1981, a deadly outbreak of disease in Spain, known as toxic oil syndrome,[28] was caused by the consumption of colza oil (a cousin of rapeseed oil procured from a similar species of B. rapa) for industrial use that was fraudulently sold as olive oil to be consumed in cooking, salads, and other foods. Symptoms appeared as a typical pneumonia with interstitial infiltrates on chest X-ray, complicated by pulmonary hypertension in a significant number of cases.[29] | Rapeseed pollen contains known allergens.[30][31] Whether rape pollen causes hay fever has not been well established, because rape is an insect-pollinated (entomophilous) crop, whereas hay fever is usually caused by wind-pollinated plants. The inhalation of oilseed rape dust may cause asthma in agricultural workers.[32] Purity wanted (per header & FCC). Purity found (low risk / cross-credit NSF) |
| Raw 2 Isohexane CAS107-83-5, HSR003332 from Univar 42% Raw 2 Solvent | NZIoC HSR00xxxx returned. AICS returned no 2nd notification. FDA21CFR173.270 25 ppm in spice oleoresins, 2.2% in hops extracts, OSHA PEL TWA 50 ppm etc. Volatile and even incidental residue <0 ppb FSANZ 1.3.3.3 white mineral oil. FSANZ 1.3.1 & 1.3.3.13 lower alkanes permitted propellant and extraction agents | Purity wanted (per header & FCC). Purity found (low risk / cross-credit NSF) |
| LPG Propellant Propane / Butane 106-97-8 HSR000989 & 1,3-Butadiene is <0.1% total 50% Raw 3 Propellant HC | 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 1.3.1 & 1.3.3.13 lower alkanes permitted propellant and extraction agents FSANZ 1.3.3 Miscellaneous additives permitted in accordance with GMP in processed foods specified in the schedule & this cross-credits to processing aids. | Purity wanted (per header & FCC). Purity found (low risk / cross-credit NSF, 3rd component trace low risk) |
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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 John Sokolich,

Please find attached the assessment report for any questions or corrections and the invoice and web listing should follow.

Ambersil Non Silicone Release FG

- Product description: release agent
- Product use: food areas as mould release agent M1
- Status: passed assessment factory new with formula, label, & NSF 149689 certificate for M1 mould release contact. Cost was \$280+GST for 1:45 hours.

"Passed AsureQuality assessment for food/beverage/dairy factory mould release contact" H3994 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 mould release contact with a minimum quantity/ transfer (compare <21CFR178.3570 values of hydrocarbon <10 mg/kg, silicone here <1 mg/kg).
- The assessment is subject to notification of change and expires on 19/06/2023.
- The full report is attached for supplier review and verification. The assessment is activated by countersigning.

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