

19/06/2018 H3996

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To whom it may concern,


Ambersil Clear Mould Protective FG

- Product description: protective coating
- Product use: protective coating in food areas

"Passed AsureQuality assessment for food/beverage/dairy with residue removed & surface sanitary before food contact " H3996 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 use as residual surface protectant with residue removed & surface sanitary before food contact (MPI non-dairy C26 says removed, NSF 149688 H2 non-contact, 21CFR 178.3570 may be incidental contact).
- 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 (MPI non-dairy C26 says removed, NSF 149688 H2 non-contact, New AsureQuality Assessment.).
- Food safety (MPI non-dairy C26 says removed, NSF 149688 H2 non-contact, 21CFR 178.3570 may be incidental contact Purity unfound low risk & questionable cross-credit NSF registration in this case).
- QA (n/a per non-food area use).
- QC specs (Chemical food safety is per raw materials as above. Micro safety is per manufacture condition & anhydrous formula & instruction to leave surface sanitary).
- Instructions –
- Label (Ambersil. Clear Mould Protective. Food Processing Safe (NSF Non-food programs listed H2 registration 149688. Transparent corrosion inhibitor. . AsureQuality approved Passed AsureQuality Assessment, MPI approved C26 - all animal products except dairy. Company contacts. "Clear, non-staining, non-silicone dry film that displaces moisture & protects against corrosion. 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, Propane-2-ol).
- TDS (CLEAR MOULD PROTECTIVE TRANSPARENT, COMPLETE ANTI-CORROSION PROTECTION CLEAR MOULD PROTECTIVE has been specially formulated for application to mould surfaces after their use to remove any surface moisture and to protect the mould against corrosion during storage. APPLICATIONS A clear, non-silicone, protective coating for use on moulds and other metallic parts and components. The transparent, dry film is non-staining and is highly recommended for use with white or clear polymers. The film will not harden or crack and is easily 'moulded-off' when recommencing production. Alternatively, the film can be easily removed using Ambersil Mould Cleaner or Amberkleen FE10, ME20 or L030. Apply an even coating to all surfaces to be protected from 9" - 12" (25 - 30cm). Ensure that the surfaces have cooled to below 35oC to ensure optimum film formation).
- 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 (Is per claim & chemical properties and otherwise outside of scope)

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)

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 (MPI non-dairy C26 says removed, NSF 149688 H2 non-contact, New AsureQuality Assessment.).

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) Ambersil Clear Mould Protective FG H3996 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. Clear Mould Protective. Food Processing Safe (NSF Non-food programs listed H2 registration 149688. Transparent corrosion inhibitor. . AsureQuality approved Passed AsureQuality Assessment, MPI approved C26 - all animal products except dairy. Company contacts. "Clear, non-staining, non-silicone dry film that displaces moisture & protects against corrosion. 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, Propane-2-ol).	TDS (CLEAR MOULD PROTECTIVE TRANSPARENT, COMPLETE ANTI-CORROSION PROTECTION CLEAR MOULD PROTECTIVE has been specially formulated for application to mould surfaces after their use to remove any surface moisture and to protect the mould against corrosion during storage. APPLICATIONS A clear, non-silicone, protective coating for use on moulds and other metallic parts and components. The transparent, dry film is non-staining and is highly recommended for use with white or clear polymers. The film will not harden or crack and is easily 'moulded-off' when recommencing production. Alternatively, the film can be easily removed using Ambersil Mould Cleaner or Amberkleen FE10, ME20 or L030. Apply an even coating to all surfaces to be protected from 9" - 12" (25 - 30cm). Ensure that the surfaces have cooled to below 35oC to ensure optimum film formation.)

HACCP analysis of other aspects	Information status & prior registrations (MPI non-dairy C26 says removed, NSF 149688 H2 non-contact, New AsureQuality Assessment.). Food safety (MPI non-dairy C26 says removed, NSF 149688 H2 non-contact, 21CFR 178.3570 may be incidental contact Purity unfound low risk & questionable cross-credit NSF registration in this case). QA (n/a per non-food area use). QC specs (Chemical food safety is per raw materials as above. Micro safety is per manufacture condition & anhydrous formula & instruction to leave surface sanitary).	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 (Is per claim & chemical properties and otherwise outside of scope)
Formulation 100% made up of components listed below		
Raw 1 Natural protective oil	NZIoC single component under appropriate group & no hazards listed. AICS human health tier 1 & no 2nd notification. FDA 21 CFR 172.615 direct food additive in chewing gum & FSANZ Food Code unfound.	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)
Raw 4 Hydrocarbon oil	NZIoC as single component under group standard. AICS human health tier 1 no 2nd notification. 21 CFR.178.3530 Lubricants with incidental contact... addition to food must not exceed 10 ppm...21 CFR. 178.3620 etc for further purified... Similar only to FSANZ 1.2.1 direct ingredient for process food is petrolatum or petroleum jelly connects to FSANZ 1.3.3 ..1.3.9 permitted lubricants.	Purity wanted (per header & FCC). Purity found (low risk / cross-credit NSF)
Raw 5 Solvent	NZIoC & AICS not returned. Dimer of material in FDA 21 CFR to no residue or 30 ppm in spice & similarly lost to evaporation. .	Purity wanted (per header & FCC). Purity found (low risk / cross-credit NSF)
Raw 6 Amine-imidazole	EPANZ if ok group standard. Internet eye skin irritant. Low toxicity >2000 mg/kg & TSCA listed. FDA 21 CFR 178.3570 lubricant with incidental contact up to 0.5% of composition. FSANZ unfound.	Purity wanted (per header & FCC). Purity found (low risk / cross-credit NSF)
Raw 7 corrosion inhibitor	EPA NZ returned HSR00xxxx ok. Hazards 6.3A, 6.4A, 9.1A (All), 9.1A (F), 9.1A (C), 9.1A (A). AICS no 2nd notification. FSANZ unfound. USA FDA 21CFR 178.3570 found to 0.5% of formulation.	Purity per NSF cross-registration
Micro safety per heat treated production and anhydrous vs growth & instruction to leave surfaces sanitary. .	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 (MPI non-dairy C26 says removed, NSF 149688 H2 non-contact, 21CFR 178.3570 may be incidental contact Purity unfound low risk & questionable cross-credit NSF registration in this case).

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

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(CRC Industries) Ambersil Clear Mould Protective FG H3996 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. Clear Mould Protective. Food Processing Safe (NSF Non-food programs listed H2 registration 149688. Transparent corrosion inhibitor. AsureQuality approved Passed AsureQuality Assessment, MPI approved C26 - all animal products except dairy. Company contacts. "Clear, non-staining, non-silicone dry film that displaces moisture & protects against corrosion. 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, Propane-2-ol).	TDS (CLEAR MOULD PROTECTIVE TRANSPARENT, COMPLETE ANTI-CORROSION PROTECTION CLEAR MOULD PROTECTIVE has been specially formulated for application to mould surfaces after their use to remove any surface moisture and to protect the mould against corrosion during storage. APPLICATIONS A clear, non-silicone, protective coating for use on moulds and other metallic parts and components. The transparent, dry film is non-staining and is highly recommended for use with white or clear polymers. The film will not harden or crack and is easily 'moulded-off' when recommencing production. Alternatively, the film can be easily removed using Ambersil Mould Cleaner or Amberkleen FE10, ME20 or L030. Apply an even coating to all surfaces to be protected from 9" - 12" (25 - 30cm). Ensure that the surfaces have cooled to below 35oC to ensure optimum film formation.).
HACCP analysis of other aspects	Information status & prior registrations (MPI non-dairy C26 says removed, NSF 149688 H2 non-contact, New AsureQuality Assessment.). Food safety (MPI non-dairy C26 says removed, NSF 149688 H2 non-contact, 21CFR 178.3570 may be incidental contact Purity unfound low risk & questionable cross-credit NSF registration in this case). QA (n/a per non-food area use). QC specs (Chemical food safety is per raw materials as above. Micro safety is per manufacture condition & anhydrous formula & instruction to leave surface sanitary).	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 (Is per claim & chemical properties and otherwise outside of scope)
Formulation 100% made up of components listed below		
Lanolin anhydrous CAS 8006-54-0 from NK Chemicals x 6.5% Raw 1 Natural protective oil	NZIoC single component under appropriate group & no hazards listed. AICS human health tier 1 & no 2nd notification. FDA 21 CFR 172.615 direct food additive in chewing gum & FSANZ Food Code unfound.	Purity wanted (per header & FCC). Purity found (low risk / cross-credit NSF)
Raw 2 Isohexane CAS107-83-5, HSR003332 from Univar 36.5% 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)
White Mineral oil CAS 8042-47-5 from Total x 2.5% Raw 4Hydrocarbon oil	NZIoC as single component under group standard. AICS human health tier 1 no 2nd notification. 21 CFR.178.3530 Lubricants with incidental contact... addition to food must not exceed 10 ppm...21 CFR. 178.3620 etc for further purified... Similar only to FSANZ 1.2.1 direct ingredient for process food is petrolatum or petroleum jelly connects to FSANZ 1.3.3 ..1.3.9 permitted lubricants.	Purity wanted (per header & FCC). Purity found (low risk / cross-credit NSF)
Diacetone alcohol CAS 123-42-4 from Univar x 1% Raw 5 Solvent	NZIoC & AICS not returned. Dimer of material in FDA 21 CFR to no residue or 30 ppm in spice & similarly lost to evaporation.	Purity wanted (per header & FCC). Purity found (low risk / cross-credit NSF)
Amine O Oleyl substituted imidazoline CAS 95-38-5 from Ciba 0.5% Raw 6 Amine-imidazole	EPANZ if ok group standard. Internet eye skin irritant. Low toxicity >2000 mg/kg & TSCA listed. FDA 21 CFR 178.3570 lubricant with incidental contact up to 0.5% of composition. FSANZ unfound.	Purity wanted (per header & FCC). Purity found (low risk / cross-credit NSF)
N -Methyl-N-(1-Oxo-9-octadecenyl)glycine CAS 110-25-8 HSR004071 from Leyhoss UK x 0.5% Raw 7 corrosion inhibitor	EPA NZ returned HSR00xxxx ok. Hazards 6.3A, 6.4A, 9.1A (All), 9.1A (F), 9.1A (C), 9.1A (A). AICS no 2nd notification. FSANZ unfound. USA FDA 21CFR 178.3570 found to 0.5% of formulation.	Purity per NSF cross-registration

Micro safety per heat treated production and anhydrous vs growth & instruction to leave surfaces sanitary. .	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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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 Clear Mould Protective FG

- Product description: protective coating
- Product use: protective coating in food areas
- Status: passed assessment factory new with formula, label, & NSF 149688 certificate for H2 mould release contact. Cost was \$320 +GST for 2 hours.

"Passed AsureQuality assessment for food/beverage/dairy with residue removed & surface sanitary before food contact " H3996 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 use as residual surface protectant with residue removed & surface sanitary before food contact (MPI non-dairy C26 says removed, NSF 149688 H2 non-contact, 21CFR 178.3570 may be incidental contact).
- The assessment is subject to notification of change and expires on 19/06/2023.
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Prepared by Global Proficiency for AsureQuality Ltd.. *R G Hutchinson*