

31/05/2016 H3636

Global Proficiency Ltd for AsureQuality Ltd,
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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,

Ados Food Grade Silicone Sealant Titania

- Product description: sealant (with fungicide)
- Product use: food area use

Passed AsureQuality assessment for food/beverage/dairy factory food areas non-contact H3636 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, GMP, & legislation as sealants for non-contact in Cool Room/ Food Areas non-contact but may be near food.
- The assessment is subject to notification of change (e.g. in formulation, raw materials or instructions) and expires on 31/05/2021).
- 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 C82 & extends existing AsureQuality assessment).
- Food safety (is by food listings/ safety data for raw material monomers or components of polymer partly from EPA NZ. Raw 8 may be negatively listed on a food packaging list but level is low & this is non-contact).
- QA & QC (ISO 9000 etc. is not required in this application. Micro safety is per antifungal and SGS test data on resistance to fungal growth for 28 days for Aspergillus niger ATCC 9642, Penicillium pinophilum ATCC 11797, Chaetomium globosum ATCC 6205, Gliocladium virens ATCC 9645, & Aureobasidium pullulans ATCC 15233).
- Instructions
- (Label CRC Ados. Food Grade Silicone Sealant neutral cure, Titania . AsureQuality approved food/ beverage/ dairy. MPI approved C82 non-dairy animal products packaging with non-contact. 100% Silicone. Mould & mildew resistant. Indoor & outdoor use. Low odour. UV resistant. Ideal for refrigerated rooms or commercial kitchens. . A low modulus silicone joint sealant with 100% neutral cure. This highly flexible sealant contains additives to resist mould & mildew, with excellent adhesion to plastics, ceramics, stainless steel, metals & glass. For use in food, pharmaceutical & other clean environments where MPI & NZ AsureQuality certification is required, ideal for refrigerated rooms or household & commercial kitchens. Use directions are fully detailed & more detail for wet surfaces. Warning causes dye & skin irritation, avoid breathing vapour, use with adequate ventilation, wear suitable protective clothes, gloves & eye protection & wash hands thoroughly after handling. Panels completed for first aid and company contacts. Food grade sealant will seal on non-porous surfaces such as glass, metal, & tiles but adhesion to porous surfaces, cement & timber may not be possible if wet)
- Technical Reference previous 01/06/2004 (On mildew prevention with sanitary silicone sealant - provides detailed information).
- Technical data sheet previous (provides technical data on the product & need for periodic replacement because of slow depletion of anti-microbial).
- MSDS previous (HSNO - hazardous substance. Signal warning. H317 May cause allergic skin reaction. Ados sealant toxicity data not available)
- Unwanted effects (Are not expected per food safety data, reported low odour, fungal resistance and distancing for non-contact in food areas).
- Sealant performance (is beyond the scope of this report).

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 (MPI C82 & extends existing 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 Ltd) Ados Food Grade Silicone Sealant Titania H3636 31-05-2016	Registrations column. Scope: NZ checks (NICNAS AICS/ EPA NZIoC, 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 PER NSF CROSS-CREDIT equivalent to normal 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.
NACCP analysis of instructions/ GMP	Instructions (Label CRC Ados. Food Grade Silicone Sealant neutral cure, Titania . AsureQuality approved food/ beverage/ dairy. MPI approved C82 non-dairy animal products packaging with non-contact. 100% Silicone. Mould & mildew resistant. Indoor & outdoor use. Low odour. UV resistant. Ideal for refrigerated rooms or commercial kitchens. . A low modulus silicone joint sealant with 100% neutral cure. This highly flexible sealant contains additives to resist mould & mildew, with excellent adhesion to plastics, ceramics, stainless steel, metals & glass. For use in food, pharmaceutical & other clean environments where MPI & NZ AsureQuality certification is required, ideal for refrigerated rooms or household & commercial kitchens. Use directions are fully detailed & more detail for wet surfaces. Warning causes dye & skin irritation, avoid breathing vapour, use with adequate ventilation, wear suitable protective clothes, gloves & eye protection & wash hands thoroughly after handling. Panels completed for first aid and company contacts. Food grade sealant will seal on non-porous surfaces such as glass, metal, & tiles but adhesion to porous surfaces, cement & timber may not be possible if wet)	Technical Reference previous 01/06/2004 (On mildew prevention with sanitary silicone sealant - provides detailed information). Technical data sheet previous (provides technical data on the product & need for periodic replacement because of slow depletion of anti-microbial). MSDS previous (HSNO - hazardous substance. Signal warning. H317 May cause allergic skin reaction. Ados sealant toxicity data not available)
HACCP analysis of other aspects	Information status & prior registrations (MPI C82 & extends existing AsureQuality assessment). . Food safety (is by food listings/ safety data for raw material monomers or components of polymer partly from EPA NZ. Raw 8 may be negatively listed on a food packaging list but level is low &	Unwanted effects (Are not expected per food safety data, reported low odour, fungal resistance and distancing for non-contact in food areas). Sealant performance (is beyond the scope of this report).

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Standard: Old Dairy Industry Standard coatings checklist for which the critical element here is "does not release toxic material" as addressed in paragraphs below.	Coatings Standard for non-contact application (per previous MQM1 Approvals Manual lists): Monitor and advise any unsatisfactory performance (to authors). Clean-ability: able to be adequately cleaned by normal procedures (for that area of the premises) without damage to the surface. Free from cracks, crevices and have no soil collection areas. Resistant to water and water vapour. Resistant (including sheet wallboard jointers) with a low rate of moisture movement. Resistant to foods e.g. milk, cream, milk fat, whey, lactic acid, etc.	Resistant to chemicals (to 10% Sodium hydroxide, nitric acid, phosphoric acid, sulphuric acid, iodophors, QAC, etc. Toxicity: does not release toxic material under finished use conditions. Durability to (chipping, flaking, or delamination. (Normal) heat and water, Machinery vibration. And regular cleaning and sanitising. Resistant to impact, to thermal shock etc. (including jointers to NZDRI criteria +/- 5mm or if climate controlled +/- 2mm). Accounting for combinations of dry/wet, hot/cold, and severe conditions. Additional general assessment checks
Raw 1 Polymer	NICNAS AICS secondary notification n/a. EPA NZ listed & HSR003459 6.4A eye irritant, 9.4A very eco-toxic to terrestrial invertebrates. Man transient conjunctival irritation. Similar material has FSANZ FS Code 1.3.3.9 permitted lubricants, release and anti-stick agents & food residue within GMP & 1.3.3 unfound & 1.3.34 antifoam only found. 21CFR 173.340 defoamer 300-1050 cst/srC to 10 ppm not milk. 178.3570 similarly >300 cst addition to food not to exceed 1 ppm/ 21 CFR 181.28 prior sanctioned food ingredients release agents 21 CFR 178.3570 300-600 cst/ 25C. NSF non-food programmed similar Silicone fluid AK350 & Wacker Silicone Fluid AD350, NSF H1 #135730, 135731.	Purity wanted (per column header). Purity found (Unfound & unrequired for this application).
Raw 2 Polymer	NICNAS AICS secondary notification n/a. EPA NZ listed & HSR003036 9.4A very eco-toxic to terrestrial invertebrates. Material has FSANZ FS Code 1.3.3.9 permitted lubricants, release and anti-stick agents & food residue within GMP & 1.3.3 unfound & 1.3.34 antifoam only found. 21CFR 173.340 de-foamer 300-1050 cst/srC to 10 ppm not milk. 178.3570 similarly >300 cst addition to food not to exceed 1 ppm/ 21 CFR 181.28 prior sanctioned food ingredients release agents 21 CFR 178.3570 300-600 cst/ 25C. NSF non-food programmed similar Silicone fluid AK350 & Wacker Silicone Fluid AD350, NSF H1 #135730, 135731.	Purity wanted (per column header). Purity found (Unfound & unrequired for this application).
Raw 3 Paraffinic HC	NICNAS AICS listed as not assessed. EPA NZ under Group Standard. Similar material This is per ANHMRC. FSANZ FS Code 1.3.1 schedule 2 SIMILAR FOUND & crosses to 1.3.3.3 and 1.3.3.11 (where NOT FOUND). NZDWS MAV NOT FOUND. 21CFR FOUND as direct food additive and processing aid.	Purity wanted (is per the column header) Purity found (is per aromatics loss by hydro-treating).
Raw 4 filler	EPA NZ under Group Standard FDA21CFR172.480 (178.3570 equiv.) & FSANZ FS Code 1.3.1 schedule 2 direct ingredient for processed food. Also 172.480	Purity wanted (per column header). Purity found (Unfound & unrequired for this application).
Raw 5 curing agent	EPA NZ under Group Standard & w/o toxicity data & FDA 21 CFR & FSAN Z FS Code unfound	Purity wanted (per column header). Purity found (Unfound & unrequired for this application).
Raw 6 curing agent	EPA NZ under Group Standard & w/o toxicity data. FDA21CFR & FSANZ FS Code unfound	Purity wanted (per column header). Purity found (Unfound & unrequired for this application).
N Raw 7 sealant	EPA NZ under no HSR003831 w/o exclusions. 9.1C harmful in the aquatic environment. FDA21CFR & FSANZ FS Code unfound	Purity wanted (per column header). Purity found (Unfound & unrequired for this application).
Raw 8 antifungal	EPA NZ under no HSR003610 w/o exclusions. 6/1B acutely toxic (inhalation and oral). 6.1C Acutely toxic (skin) 6.3A Irritating to skin. 6.4A Irritating to eyes. 6.9A oral toxicity to human target organs/ systems. 9.1A Very eco-toxic to aquatics. 9.3A Very eco-toxic to terrestrial vertebrates. FDA21CFR & FSANZ FS Code unfound WHO report NOAELs for mono- and dioctyl-tin have been determined to be 0.87 and 0.23 mg/kg body weight per day, respectively, although the value for mono-octyltin is an estimate, because the study was performed using a mixture. Other information suggests that dioctyltin is the more immune-toxic of the two compounds. Brief	Of the reported unintentional occupational exposures, none has an estimate of exposure concentration. Exposure was largely via the inhalation route, with some possibility of dermal exposure. Neurological effects were the most commonly reported, and these can persist for long periods. Reliable lifetime TDI values cannot be derived, since long-term studies at the appropriate doses and in the appropriate species are not available. Medium-term exposure TDIs for the estimation of risk were estimated (as the chlorides) as 0.0012 mg/kg body weight for mono-methyl-tin and di-methyl-tin based on neurotoxicity,

	<p>summaries were available for unpublished long-term studies for some of the organo-tins under consideration. These showed no carcinogenicity for mixtures of mono- and dimethyl-tins in rats and mono- or dioctyl-tins in rats or dogs except for a single study on a mixture of mono- and dioctyltin chlorides. This showed significantly increased frequency of thymic lymphomas in female rats only at the 150 mg/kg diet dose. Significant increases were seen in the incidence of generalized malignant lymphomas in males of the 50 and 150 mg/kg groups, but only in females at the highest dose. Very few data are available on the effects of organo-tins in humans.</p>	<p>0.003 mg/kg body weight for dibutyl-tin based on immune-toxicity, and 0.002 mg/kg body weight for dioctyltin, also based on immune-toxicity. No reliable TDI could be derived for monobutyl-tin or monoocetyl</p>
<p>Pathogens needing to be controlled are listed here with pH growth ranges</p>	<p>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,</p>	<p>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</p>

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Hydroxy-terminated polydimethylsiloxane CAS 70131-67-8 from Vital Technica 65% Raw 1 Polymer	NICNAS AICS secondary notification n/a. EPA NZ listed & HSR003459 6.4A eye irritant, 9.4A very eco-toxic to terrestrial invertebrates. Man transient conjunctival irritation. Similar material has FSANZ FS Code 1.3.3.9 permitted lubricants, release and anti-stick agents & food residue within GMP & 1.3.3 unbound & 1.3.34 antifoam only found. 21CFR 173.340 defoamer 300-1050 cst/srC to 10 ppm not milk. 178.3570 similarly >300 cst addition to food not to exceed 1 ppm/ 21 CFR 181.28 prior sanctioned food ingredients release agents 21 CFR 178.3570 300-600 cst/ 25C. NSF non-food programmed similar Silicone fluid AK350 & Wacker Silicone Fluid AD350, NSF H1 #135730, 135731.	Purity wanted (per column header). Purity found (Unfound & un-required for this application).
Polydimethylsiloxane CAS 63148-62-9 from Vital Technica 15% Raw 2 Polymer	NICNAS AICS secondary notification n/a. EPA NZ listed & HSR003036 9.4A very eco-toxic to terrestrial invertebrates. Material has FSANZ FS	Purity wanted (per column header). Purity found (Unfound & un-required for this application).

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email sokolichj@crc.co.nz

Global Proficiency Ltd for AsureQuality Ltd,
Ruakura Research Centre, Hamilton East,
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. This is a cover letter and not part of the report.

Ados Food Grade Silicone Sealant Titania

- Product description: sealant (with fungicide)
- Product use: food area use
- Status: This passed extension of AsureQuality assessment for factories cost \$125 + GST 0:50 hour on 31/05/2016. The antimicrobial does have prohibitions but we added WHO data).

Passed AsureQuality assessment for food/beverage/dairy factory food areas non-contact H3636 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).

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