03/07/2017 H2439

Sika (NZ) Ltd, P O Box 19-192 Avondale Auckland 1748, 85-91 Patiki Rd Avondale, Auckland 1028. Ph 09 820 2900, fax 09 828 4091 Contact Mike Edwards edwards.mike@nz.sika.com

Global Proficiency Ltd for AsureQuality Ltd,
3-5 Lillee Cres. Tullamarine Vic 3043,
Australia +61 3 83189014
Global Proficiency Ltd for AsureQuality Ltd,
Ruakura Research Centre, Hamilton East,
P O Box 20474 Hamilton

To whom it may concern,

Sika (NZ) Ltd - Sikaflex 11-FC, Sikadur-51, Sikaflex AT-Façade, *Sikasil C (ex Sikaflex C)

- Product description: joint sealants / adhesives
- Product use: Sikaflex 11-FC cold potable water, & all 4 products for food area use

"Passed AsureQuality assessment for food/beverage/dairy factory food areas non-contact plus for Sikaflex 11-FC cold potable water contact H2439 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, as sealants in Cool Room/ Food Areas non-contact /may be near food plus Sikaflex 11-FC also suits cold potable water.
- The assessment is subject to notification of change and expires on 03/07/2022).
- 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:..... 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 (All had 5 years use since previous AsureQuality assessment. All had HSN HSR00xxxx registration and all components listed or comply with NZIoC. Also Sikaflex 11-FC had prior MPI approval for food areas plus it passed AS/NZS 4020:2004 potable water contact compliance tests).
- Food safety (was per no apparent risks for use food areas per PDS & SDS plus potable water safety for Sikaflex 11-FC was by normal cell growth, no Aimes reversion & no adverse taint or test on the water extract).
- QA & QC (ISO 9000 etc. is not required in this application. Micro safety is per 5 years use using routine cleaning (& antimicrobial may also be present).
- Instructions (All 4 products had updated PDS & SDS and previous product information summarised under each product in the table & this report is consistent with these).
- Unwanted effects (Are per PDS & SDS listings & HSNO clearances for each product plus all have 5 years use and Sikaflex 11-FC also passed tests for unwanted taint/tests on the water extract).
- Efficacy (Sealant performance is per PDS & 5 years of use 1 SDS. Sikaflex 11FC water extract tests. Sikdadur 51 Tested per BS 6319 & complies with ASTM C881-78 type 2 grade 2, class B &C. Sikaflax AT-Facade had DIN 13540 SKZ Wurzburg. ISO 11600 group F, class 25 LMK, SNJF, ASTM C920, Branz 613 (2008). Otherwise sealant hygiene generally speaking requires routine cleaning).

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-moderate (post-heat step)
Severity	Low	Low-high
Total	Low	Low-moderate (post-heat step)

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 (All had 5 years use since previous AsureQuality assessment. All had HSN HSR00xxxx registration and all components listed or comply with NZIoC. Also Sikaflex 11-FC had prior MPI approval for food areas plus it passed AS/NZS 4020:2004 potable water contact compliance tests).

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

(Sika (NZ) Ltd) Sikaflex 11-FC, Sikadur-51, Sikaflex AT-Façade, Sikasil C h2439 03-07-2017	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.
HACCP analysis of instructions/ GMP	Instructions (All 4 products had updated PDS & SDS and previous product information summarised under each product in the table & this report is consistent with these).	
HACCP analysis of other aspects	Information status & prior registrations (All had 5 years use since previous AsureQuality assessment. All had HSN HSR00xxxx registration and all components listed or comply with NZIoC. Also Sikaflex 11-FC had prior MPI approval for food areas plus it passed AS/NZS 4020:2004 potable water contact compliance tests). . Food safety (was per no apparent risks for use food areas per PDS & SDS plus potable water safety for Sikaflex 11-FC was by normal cell growth, no Aimes reversion & no adverse taint or test on the water extract). QA & QC (ISO 9000 etc. is not required in this application. Micro safety is per 5 years use using routine cleaning (& antimicrobial may also be present)	Unwanted effects (Are per PDS & SDS listings & HSNO clearances for each product plus all have 5 years use and Sikaflex 11-FC also passed tests for unwanted taint/tests on the water extract). Efficacy (Sealant performance is per PDS & 5 years of use 1 SDS. Sikaflex 11FC water extract tests. Sikdadur 51 Tested per BS 6319 & complies with ASTM C881-78 type 2 grade 2, class B &C. Sikaflax AT-Facade had DIN 13540 SKZ Wurzburg. ISO 11600 group F, class 25 LMK, SNJF, ASTM C920, Branz 613 (2008). Otherwise sealant hygiene generally speaking requires routine cleaning).
Standard: Old Dairy Industry Standard coatings checklist for which the critical element here is "does	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	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.

Ruakura Research Centre, Hamilton East, P O Box 20474 Hamilton, New Zealand 3241
Ph +64 7 850 4483, fax+64 7 850 4487, http://assessedproducts.asurequality.com/
Email:< bob.hutchinson@global-proficiency.com

not release toxic material" ..as addressed in paragraphs below.	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.	(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
Sika (NZ) Ltd SIKAFLEX 11FC (polyurethane)	Update 03/07/2017 Sighted PDS one component polyurethane joint flexible sealant &high strength adhesive, non-slumping, moisture cured tough & resistant polymer). SDS latter with full warnings (Flammable liquid cat D, skin irritation B, eye irritation A, respiratory sensitisation A, carcinogenicity B, STOT oral B, STOT inhalation B central nervous system, Aquatic toxicity D & Hazard pictograms. Components Xylene 1-10%, Hydrocarbons alkanes-aromatics 1-10%, Ethylbenzene 0.1-1%, & 4, 4'methylenediphenylisocyanate. 0.1-1%. Exposure controls with WES numbers listed. Toxicology similar to cautions above + suspected of causing cancer & of damage to fertility & the unborn child. Transport non-DG. Regulatory HSNO HSR002680. Components on or in compliance with NZIoC). Update also (MAF 03/08/1998 approval for Sikaflex 11 FC for meat fish game one component polyurethane elastomeric sealant). Update also (AMS Laboratories tests to AS/NZS 4020:2004 potable water contact compliance tests - fully complies to cover cold water application to 40C at total immersion of 8453 mm2/L of test water).	Past data (Concrete Floor control joints Sikaflex 11FC Sikaflex 11FC is a single component polyurethane sealant which has the following key features which identify this product as ideally suited to floor jointing applications; Excellent adhesion to concrete. Toughness and durability similar to tyre rubber. Non-staining on porous substrates Suitable for internal and external applications Suitable for foot and folk hoist traffic. Low odour and VOC content. Cures by reaction with atmospheric moisture to an elastomeric odourless compound. Suitable for permanent full immersion in water). Past data continued (Limits of application - In general Polyurethane sealant products service life is limited by the following; Will withstand short exposure to cleaning temperature of no more than 80C°.Will withstand scrubbing, however has low resistance to acid wash down. Will eventually support biological growth if regular cleaning is not carried out to remove an introduced food source. Sighted "Product data sheet", MSDS, & VOC content test certificate with 62g VOC/L. Polyurethanes - these may meet 21CFR contact requirements based on positive listing and finished form extractability)
Sika (NZ) Ltd SIKADUR 51 (epoxy resin)	Update 03/07/2017 Sighted PDS (A 2 component, joint sealing compound of flexible epoxy resins thixotropic & no slump suits trowel, spatula or gun)l. Also SDS latter with part A & B. Part A (skin irritation A, eye irritation A, skin sensitisation B, & aquatic toxicity B. Composition 1,6 bis 2,30epoxypopoxy) hexane 20-30%, Phenol 1-10%, 4-nonylphenol branched 1-10%. Toxicology similar to above. Ecology & transport lists. Regulatory HSNO HSR002670. Components on or in compliance with NZIoC). Part B (acute oral toxicity E (6.1D), skin corrosion A (8.2A), serious eye damage A (8.3A), skin sensitisation B (6.5B), aquatic toxicity C (9.1C), Eco-toxicity soil C (9.2B). Composition (Phenol methyl styrenated10-20%, Trimethylhexane-1,5-diaminie 10-20%, amino-methylhexylamine 1-10%, Trisdimethylaminomethylphenol, benzyl alcohol 1-10% and Reaction product 1-10%.Toxicology similar to above plus chronic may have no data.. Ecology & transport lists. Regulatory HSNO HSR002670Components on or in compliance with NZIoC)	Past data (Product Description: Sikadur 51Sikadur 51 is a 2 component flexible epoxy sealant which has the following key features which identify this product as ideally suited to floor jointing applications. Excellent adhesion to concrete. Toughness and durability that no single component polyurethane can achieve. Non-staining on porous substrates. Suitable for internal and external applications Suitable for foot, folk hoist traffic as well as heavy duty vehicle traffic. Very low odour and solvent content. Cures by chemical reaction between the 2 components of the product to a very hard durable compound. Limits of application Sikadur 51 sealant's service life is limited by the following Service temperature resistance of 50C°.Will withstand scrubbing; however has low resistance to acid wash down. Will eventually support biological growth if regular cleaning is not carried out to remove an introduced food source. Not suitable for permanent full immersion in water. Sighted "Product data sheet", & MSDS. Epoxy resin - these may meet 21CFR contact requirements based on positive listing and finished form extractability).
Sika (NZ) Ltd Sikaflex AT-Façade (silane terminated PU hybrid technology)	Update 03/07/2017 Sighted PDS (1 part, moisture cured, elastic sealant with polymers silane terminated. & specially formulated for movement & connection joints on porous & non-subtrates for weather-ability & UV resistance). SDS. (Warning. Composition Bis-(ethylhexyl)adipate 1-10%, Aliphatic - aromatic hydrocarbons 1-10%. Exposure controls list. Toxicology similar to above and chronic mostly no data available. Transport non-DG. Regulatory HSNO HSR002680. Components on or in compliance with NZIoC).	Past data (Concrete Wall Joint application. Product description: .Sikaflex AT-Facade is a single component hybrid polyurethane sealant which has the following key features which identify this product as ideally suited to vertical wall jointing; Excellent adhesion to a wide range of substrates including concrete. Conforms to ISO 11600 Class F 25LM. Non-staining on porous substrates. Suitable for internal and external applications Very low odour and VOC content. Cures by reaction to atmospheric moisture to an elastomeric odourless compound. Limits of application In general Polyurethane sealant products service life is limited by the following; Will withstand short exposure to cleaning temperature of no more than 80C°.Will withstand scrubbing, however has low resistance to acid wash down. Will eventually support biological growth if regular cleaning is not carried out to remove an introduced food source. Sighted "Product data sheet", & MSDS. VOC cert for 18g/L. Polyurethanes - these may meet 21CFR contact requirements based on positive listing and finished form extractability.)
Sika (NZ) Ltd Sikasil C	Update 03/07/2017 Sighted PDS (low modulus neutral cure silicone refrigeration sealant & SDS (Non-hazardous	Past data (Product description: Sikasil C is a single component neutral cure silicon sealant which has

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Ph +64 7 850 4483, fax+64 7 850 4487, http://assessedproducts.asurequality.com/
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	substance or mixture. Composition (aliphatic-aromatic hydrocarbons 1-10%, Sil-sequioxanes, 3-aminomethyl ethoxy terminated 1-10%, Exposure controls listed. Toxicology similar to above and chronic mostly no data available Transport non-DG. Regulatory HSNO HSR00?. Components on or in compliance with NZIoC)	the following key features which identify this product as ideally suited to vertical cool store panel jointing. Excellent adhesion to a wide range of substrates including Cool store panel. Resistance to biological growth. NZSFA approval. Suitable for internal and external applications Low odour and VOC content. Cures by reaction to atmospheric moisture to an elastomeric odourless compound. Limits of application. In general Polyurethane sealant products service life is limited by the following; Greater Chemical resistance than Polyurethane. Will possibly cause silicone oil staining of porous substrates such as concrete. Low resistance to mechanical damage from scrubbing. Does not possess the durability or toughness required for applications where there is high mechanical movement stress or resistance to abrasion is required. Sighted "Product data sheet", & MSDS,
pH high vs growth of pathogens at ranges here.	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 enterolytica 4.4-9.6

- Food safety (was per no apparent risks for use food areas per PDS & SDS plus potable water safety for Sikaflex 11-FC was by normal cell growth, no Aimes reversion & no adverse taint or test on the water extract).

12 The formulation in confidence & not for public circulation normally follows but there is not sensitive data in this case.

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Global Proficiency Ltd for AsureQuality Ltd,
3-5 Lillee Cres. Tullamarine Vic 3043,
Australia +61 3 83189014
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Dear Mike Edwards

Please find attached to this cover letter - your assessment report to please advise any questions and suggestions. The invoice and web listing will follow.

Sika (NZ) Ltd - Sikaflex 11-FC, Sikadur-51, Sikaflex AT-Façade, *Sikasil C (ex Sikaflex C)

- Product description: joint sealants / adhesives
- Product use: Sikaflex 11-FC cold potable water, & all 4 products for food area use
- Status: This passed AsureQuality assessment for factories cost $375 + GST 2.5 hours. Based PDS & SDS, past data, & for Sikaflex 11-FC on lab testing for cold potable water contact.

"Passed AsureQuality assessment for food/beverage/dairy factory food areas non-contact plus for Sikaflex 11-FC cold potable water contact H2439 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, as sealants in Cool Room/ Food Areas non-contact /may be near food plus Sikaflex 11-FC also suits cold potable water.
- The assessment is subject to notification of change and expires on 03/07/2022).
- The full report is attached for supplier review and verification. The assessment is activated by countersigning."

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