

10/04/2017 reference H3830

Global Proficiency Ltd for AsureQuality Ltd,
Ruakura Research Centre, Hamilton East,
P O Box 20474 Hamilton.

Chemetall NZ Ltd, 664 Rosebank Rd, Avondale, Auckland
1026. P O Box 15783 New Lynn, Auckland, NZ. Phone 09 820
3888, fax -3979. Attention Trevor Davies trevor.davies@chemetall.com

To whom it may concern,

Ardrox 9D1B

- Product description: non-aqueous wet developer - solvent
- Product use: with Ardrox Red & Fluorescent Dye Colouring Systems used to detect cracks & porosity in all kinds of metal components

Passed AsureQuality assessment for food/beverage/dairy factory food areas including contact surfaces H3830 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 food areas & contact surfaces areas with residues removed (must add residue removal instruction).
- Usage /carry-over to food - this should be removed per the nature of this use.
- The assessment is subject to notification of change and expires on 10/04/2022).
- 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:

- Prior registrations (AsureQuality assessment new. NSF unfound. MSDS Regulatory says all ingredients on AICS and no poison allocation).
- Food safety (is incomplete with most raw material similar to food safety listings/ residues within limits w/o purity but mainly depends on residue removal after inspection).
- QA (not found or required).
- QC specs (Chemistry is as above. Micro is probably based on anhydrous formulation & isopropanol level).
- Instructions –
 - Chemetall label (Ardrox 9D1B non-aqueous wet developer - solvent. Risk - Irritating to eyes. Repeated exposure may cause skin dryness or cracking. Vapours may cause drowsiness & dizziness. Lists for safety, first aid, spills/leaks fire and contains 60% acetone, 10-30% isopropanol. Flammable. Company contacts).
 - Product Profile (Ardrox 9D1B. suspension of inert white powder in quick drying solvent. It has low Sulphur, Halogen, and Alkali metal content and can be used with any Ardrich cleaners & visible and fluorescent penetrants. After suitable pre-cleaning & penetrant application, removal & drying of components, this is 9D1B is applied by spraying. Agitate suspension. Spray to given even thin white film over inspection surface for 10 minutes and components are then inspected by good light for red components and UV light for fluorescent components. Flash point is -18C).
 - MSDS (Hazardous per NOHSC Australia. Hazardous substance. Dangerous Good. R36 irritating to eyes, R66 repeat exposure may cause skin drying or cracking. R67 Vapours may cause drowsiness 7 dizziness. Composition - Acetone >60% Isopropanol 10-30%. & other ingredients non-hazardous per NOHSC criteria. Exposure controls for Acetone & Isopropanol. Toxicology acute effects per hazards above & Chronic says prolonged or repeat exposure may lead to dermatitis & no other data available. Ecology no data available. Transport has Flammable & detailed list. Regulatory says all ingredients on AICS and no poison allocation).
- Unwanted effects (OSH covered by SDS of finished product + RM data + AICS cleared RMS & NZIoC mostly cleared RMs).
- Efficacy (is by claim & crack & porosity testing are outside of scope).

Contents Sections 3-11 are omitted in favour of the summary on the first page.

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 after heat step)
Severity	Low	Low
Total	Low	Low (moderate after 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 inc “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).

- Prior registrations (AssureQuality assessment new. NSF unfound. MSDS Regulatory says all ingredients on AICS and no poison allocation).

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

(Chemetall NZ Ltd) Ardrex 9D1B H3830 10-04-2017	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 analysis and instructions summary	Chemetall label (Ardrex 9D1B non-aqueous wet developer - solvent. Risk - Irritating to eyes. Repeated exposure may cause skin dryness or cracking. Vapours may cause drowsiness & dizziness. Lists for safety, first aid, spills/leaks fire and contains 60% acetone, 10-30% isopropanol. Flammable. Company contacts). Product Profile (Ardrex 9D1B. suspension of inert white powder in quick drying solvent. It has low Sulphur, Halogen, and Alkali metal content and can be used with any Ardrex cleaners & visible and fluorescent penetrants. After suitable pre-cleaning & penetrant application, removal & drying of components, this is 9D1B is applied by spraying. Agitate suspension. Spray to given even thin white film over inspection surface for 10 minutes and components are then inspected by good light for red components and UV light for fluorescent components. Flash point is -18C).	MSDS (Hazardous per NOHSC Australia. Hazardous substance. Dangerous Good. R36 irritating to eyes, R66 repeat exposure may cause skin drying or cracking. R67 Vapours may cause drowsiness 7 dizziness. Composition - Acetone >60% Isopropanol 10-30%. & other ingredients non-hazardous per NOHSC criteria. Exposure controls for Acetone & Isopropanol. Toxicology acute effects per hazards above & Chronic says prolonged or repeat exposure may lead to dermatitis & no other data available. Ecology no data available. Transport has Flammable & detailed list. Regulatory says all ingredients on AICS and no poison allocation).
HACCP analysis and other aspects	Prior registrations (AssureQuality assessment new. NSF unfound. MSDS Regulatory says all ingredients on AICS and no poison allocation). Food safety (is	Unwanted effects (OSH covered by SDS of finished product + RM data + AICS cleared RMS & NZIoC mostly cleared RMS). Efficacy (is by claim & crack &

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

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Formulation 100%	See RMs below AICS cleared RMS & NZIoC mostly cleared RMs	
Isopropanol CAS 67-63-0 NZIoC HSR001180 ok from Redox 21.5% Raw 1 Alcohol	NZIoC HSR00xxxx ok. USA as yardstick: FDA 21 CFR 182.1073 USDA 9 CFR 318.7, .147 to 0.01% in fats. Toxicity: OSHA PEL; TWA 1mg/metre cubed etc. FSANZ Food Code 2000 1.3.3.10 permitted carriers solvents – and the level of contact here is lower. USAFDA21CFR73.1, 173.240 as extractant etc. for beet sugar etc. and use in manufacturing process is community right to know and EPA genetic toxicity programme (and the level here is expected to be much lower). OSHA PEL TWA 400 mg/kg. Poison by ingestion & subcutaneous, mod toxic by intraperitoneal, & intravenous routes and mild by dermal. Purity is per activity & also MSDS sighted.	Side effects are not expected according to ready degradability and low toxicity. ERMNZ Classn ok. Purity wanted per column header & FSANZ refer FCC7 2010-2011 GMP indicators unfound. Purity found (not found or required for this application).
Acetone CAS 67-64-1 EPANZ HSR001070 ok from Axio Specialties 66.5% Raw 2 paraffinic ketone	NICNAS AICS (listed as not assessed). EPANZ HSR001070 ok. & no exclusions. 21CFR food use as colour diluent extractant solvent e.g. for spice limited to 30 ppm in spices etc. Human metabolite.	Purity wanted (per column header) Purity found (unfound/unrequired)
Amines, N-(C18 unsaturated alkyl)trimethylene diethoxylated CAS 1268344-02-0 EPA NZ HSR unfound from BASF 0.1% Raw 3 Amines	Internet in says incomplete assessment & H315 Causes skin irritation. H317 May cause an allergic skin reaction. H319 Causes serious eye irritation. H335 May cause respiratory irritation. Carcinogenicity IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. ACGIH NTP. No other data available.	Purity wanted (per column header) Purity found (unfound/unrequired)
Talc Magnesium silicate CAS 14807-96-6 from Orica - 10.2% 38.5% Raw 4 Mineral	USAFDA use as anti-cake, coating, lubricant, release agent, regulation - is not food grade if derived from deposits containing asbestiform minerals. FSANZ 1.3.3 direct ingredient.	Purity wanted (per column header). Purity found (not found or required for no residue)
Aerosil 200 Fumed silica, silicon dioxide CAS112945-52-5 from Evonik 2.1% Raw 4 thixotrope	AICS Australia & NZIoC registered under Group Standard FDA21CFR172.480 (178.3570 equivalent) & FSANZ FS Code 1.3.1 schedule 2 direct ingredient for processed food. Also 21 CFR 172.480. Reach exempt,	Purity wanted (per column header) Purity found (Wants crystalline silica below 0.5% & otherwise purity is not critical here)
pH & microbiological growth ranges - safe / 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

[illegible]

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Chemetall NZ Ltd, 664 Rosebank Rd, Avondale, Auckland
1026. P O Box 15783 New Lynn, Auckland, NZ. Phone 09 820
3888, fax -3979. Attention Trevor Davies trevor.davies@chemetall.com

Dear Trevor Davies,

Please find attached your assessment report for any questions or suggestions. This page is not part of the report or invoice which should follow.

Ardrox 9D1B

- Product description: non-aqueous wet developer - solvent
- Product use: with Ardrox Red & Fluorescent Dye Colouring Systems used to detect cracks & porosity in all kinds of metal components
- Status: passed new factory assessment. PO - . Cost \$250 + GST for 1:40 hours. .

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