

05/10/2017 H2582

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& Ruakura Research Centre, Hamilton East,
P O Box 20474 Hamilton.

To whom it may concern,
Peel Off Label Remover

- Product description: cleaner (label remover, solvent)
- Product use: food areas non-contact

"Passed AsureQuality assessment for food/beverage/dairy factory food areas non-contact" H2582 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 & non-contact (on non-permeable packaging & care - d-Limonene).
- The assessment is subject to notification of change and expires on 05/10/2022.
- 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: *[Signature]* Date: *5/10/17*

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 (Renewed AsureQuality Assessment for noncontact).
- Food safety (raw material FSANZ & 21CFR listings in table & Dutch listing favours non-contact. Purity of RMs not found or required for non-contact).
- QA (not found or required for non-contact).
- QC specs (Not found or required for non-contact. Micro safety is per manufacture condition & anhydrous formula).
- Instructions –
 - Label (Previously CRC Peel Off label remover, removes labels & adhesive, cleans off cured adhesive, cleans industrial inks off machinery. Over 90% active ingredients natural d-limonene oil. XD8 Label Remover uses the power of d-Limonene to soak through paper labels and release adhesive backings. Once released, the label can be peeled off and residue easily removed with a wet cloth. XD8 label remover is ideal for removing unwanted labels from most containers. Use in factories, processing plants, supermarkets, printing plants and industrial applications. Directions listed to shake can, spray from 15-20 cm liberal, & after allow 5 minutes to soak through and release adhesive. Peel off with hands/scrapper and remove softened adhesive with damp cloth. Cautions use with adequate ventilation, not in confined spaces and get fresh air if required. Misuse by concentrating and inhaling may be fatal. Do not puncture or incinerate even when empty. Keep away from heat, flames, & sources of ignition. Propellant hydrocarbon. Warning re fire etc. listed, NZFSA approved non-dairy animal products C101 (incomplete code & means must be use in accordance with special conditions that are specified). Manufacturer contacts found. NZFSA C101-52 means food absent from the room).
 - SDS (HSNO classification #s & phrases, hazard pictograms, GHS H222 extremely flammable aerosol, H303 may be harmful if swallowed, H313 May be harmful in contact with skin, H333 May be harmful if inhaled. H315 causes skin irritation, H319 causes serious eye irritation, H317 causes allergic skin reaction, H335 may cause respiratory irritation, H336 may cause drowsiness or dizziness, H316 very toxic to aquatic with lengthy effects. Composition d-Limonene, 30-60%, Propylene glycol mono-butyl ether 10-30%, Hydrocarbon propellant 10-30%. Lists. Exposure controls Liquified petroleum gas TWA 1800 mg/m3. Emergency limits d-Limonene 15-170 ppm, PGMPE 0.93-61 ppm, Hydrocarbon ca 65000-400,000 ppm. Toxicology as per hazards and STOT single exposure and no caution for other / chronic "icity" effects. Environmental effects, Transport requirements. Regulatory includes above & approved handler & tracking requirements).
- Side effects (Environment/OSH are per SDS & NZIoC etc. Production side effects per food safety listings. Caution flammable).
- Hygiene efficacy (is claimed and formula is consistent with this.).

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 (Renewed AsureQuality Assessment for noncontact).

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) Peel Off Label Remover H2582 05-10-2017	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 vs Instruction summary & exception reporting	Label (Previously CRC Peel Off label remover, removes labels & adhesive, cleans off cured adhesive, cleans industrial inks off machinery. Over 90% active ingredients natural d-limonene oil. XD8 Label Remover uses the power of d-Limonene to soak through paper labels and release adhesive backings. Once released, the label can be peeled off and residue easily removed with a wet cloth. XD8 label remover is ideal for removing unwanted labels from most containers. Use in factories, processing plants, supermarkets, printing plants and industrial applications. Directions listed to shake can, spray from 15-20 cm liberal, & after allow 5 minutes to soak through and release adhesive. Peel off with hands/scrapper and remove softened adhesive with damp cloth. Cautions use with adequate ventilation, not in confined spaces and get fresh air if required. Misuse by concentrating and inhaling may be fatal. Do not puncture or incinerate even when empty. Keep away from heat, flames, sources of ignition. Propellant hydrocarbon. Warning re fire etc. listed, NZFSA approved non-dairy animal products C101 (incomplete code & means must be use in accordance with special conditions that are specified). Manufacturer contacts found. NZFSA C101-52 means food absent from the room).	SDS (HSNO classification #s & phrases, hazard pictograms, GHS H222 extremely flammable aerosol, H303 may be harmful if swallowed, H313 May be harmful in contact with skin, H333 May be harmful if inhaled. H315 causes skin irritation, H319 causes serious eye irritation, H317 causes allergic skin reaction, H335 may cause respiratory irritation, H336 may cause drowsiness or dizziness, H316 very toxic to aquatics with lengthy effects. Composition d-Limonene, 30-60%, Propylene glycol mono-butyl ether 10-30%, Hydrocarbon propellant 10-30%. Lists. Exposure controls Liquified petroleum gas TWA 1800 mg/m3. Emergency limits d-Limonene 15-170 ppm, PGMPE 0.93-61 ppm, Hydrocarbon ca 65000-400,000 ppm. Toxicology as per hazards and STOT single exposure and no caution for other / chronic "icity" effects. Environmental effects, Transport requirements. Regulatory includes above & approved handler & tracking requirements).
HACCP analysis of other aspects	Information status & prior registrations (Renewed AsureQuality Assessment for noncontact). Food safety (raw material FSANZ & 21CFR listings in table & Dutch listing favours non-contact. Purity of RMs not found or required for non-contact). QA (not found or required for non-contact). QC specs (Not found or required for non-contact. Micro safety is per manufacture condition & anhydrous formula).	Side effects (Environment/OOSH are per SDS & NZIoC etc. Production side effects per food safety listings. Caution flammable). Hygiene efficacy (is claimed and formula is consistent with this.).
Formulation 100% made up of components listed below & FCS contact carryovers per farm		

model in table Raw 1 Solvent (& fragrance).	NICNAS AICS Listings Hazard means secondary notification applies. EPA NZ HSR00xxxx. Recorded as irritant avoid contact/gloves and oxidation CAS 5989-27-5, 5989-54-8, 139-86-3) Limonene & terpineol USFDA21CFR182.60 etc. as a direct flavour w/o excess, other components unfound. NICNAS AICS Listings Hazard means secondary notification applies. EPA NZ HSR00xxxx. Recorded as irritant avoid contact/gloves and oxidation CAS 5989-27-5, 5989-54-8, 139-86-3). FSANZ Food Standards Code direct food ingredient not quickly found. Similarly 21CFR 182.60 direct ingredient not in excess for effect. Over 90% exposure is by flavouring & acute & repeat air limits may be 4500 & 450 microg/m3. d-Limonene is a major constituent of citrus oils, is a monoterpene widely used as a flavour/fragrance additive in cosmetics, foods, and industrial solvents as it possesses a pleasant lemon-like odour. Pub Med d-Limonene has been designated as a chemical with low toxicity based upon lethal dose (LD50) and repeated-dose toxicity studies when administered orally to animals. Food listing/non-toxicity: food listed 21CFR182.60 direct flavouring substance and FSANZ allows permitted synthetic flavourings. Safety Limonene and its oxidation products are skin and respiratory irritants, and limonene-1,2-oxide (formed by aerial oxidation) is a known skin sensitizer. Most reported cases of irritation have involved long-term industrial exposure to the pure compound, e.g., during degreasing or the preparation of paints. However, a study of patients presenting dermatitis showed that 3% were sensitized to limonene. [20].	Although high doses have been shown to cause renal cancer in male rats, [21] limonene is considered by some researchers to be a potential chemo-preventive agent [22] with value as a dietary anti-cancer tool in humans. [23] There is no evidence for carcinogenicity or genotoxicity in humans. The IARC classifies d-limonene as a Group 3 carcinogen: not classifiable as to its carcinogenicity to humans [20][24]. FSANZ Food Standards Code direct food ingredient not quickly found. Similarly 21CFR 182.60 direct ingredient not in excess for effect. Over 90% exposure is by flavouring & acute & repeat air limits may be 4500 & 450 microg/m3. d-Limonene, a major constituent of citrus oils, is a monoterpene widely used as a flavour/fragrance additive in cosmetics, foods, and industrial solvents as it possesses a pleasant lemon-like odour. Abbreviated Lim abstract from Pub Med d-Limonene has been designated as a chemical with low toxicity based upon lethal dose (LD50) and repeated-dose toxicity studies when administered orally to animals. Purity found (physical properties + peroxide 15 (<60) meQ)
Raw 2 Solvent	NZIoC HSR# ok. Bridged between listings USAFDA21CFR178.1010 food contact surface sanitiser not necessarily rinsed or extended to dairy. FSANZ FS Code not found (only alkenyl poly-ethers). Current incomplete ID vs previous concern Chemical study on alkyl-phenols RKZ/2001.029 & note reports show feeding NOAEL 30+ mg/kg, & possible carcinogenicity & endocrine disruption mean an ADI is not set so approval is subject to reviews of this (PAN directory underestimates approvals held as USA only). IMCD MSDS Risk phrases not hazardous no criteria found, safety S23, S24/25 Do not breathe vapours or mists. Avoid contact with skin & eyes.	Toxicological information no data to hand for particular target organs. Ecological biodegradable will not accumulate or cause long term problems LC50fathead minnow 3790 mg/L, Daphnia EC50 1812 mg/L. Purity wanted (per column header). Purity found (not found or required for food areas non-contact)
Raw 3 solvent	NZIoC at 5-10% HSR006398 3.1D 6.1E (dermal) Acutely toxic Flammable Liquids: low hazard USAFDA21CFR 178.1010 food contact surface sanitiser similar, FSANZ 1.3.3.3 GP processing aid, BS 5305, IDF 9101	Side effects appear non-problematic per the food listing, ERMA scope, MSDS and IDF Bulletin 288 on environment & corrosion. Efficacy is according to the food listing above. Purity wanted (per column header). Purity found (not found or required for food areas non-contact)
Raw 4 propellant	NZIoC HSR# ok. USA FDA 21 CFR 184.1165 FOUND GRAS with GMP including as an aerating agent, gas, propellant. ACGIH TWA 800 mg/kg. Mildly toxic by inhalation. FSANZ 1.3.1 schedule 5 allows propellants but HC propellant not found - but NZ Food Regulations 1984 - similarly listed Identity and purity of supply propane, butane.	Purity wanted (per column header). Purity found (not found or required for food areas non-contact)
Micro safety per manufacture conditions & while 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

- Food safety (raw material FSANZ & 21CFR listings in table & Dutch listing favours non-contact. Purity of RMs not found or required for non-contact).

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HACCP vs Instruction summary & exception reporting	Label (Previously CRC Peel Off label remover, removes labels & adhesive, cleans off cured adhesive, cleans industrial inks off machinery. Over 90% active ingredients natural d-limonene oil. XD8 Label Remover uses the power of d-Limonene to soak through paper labels and release adhesive backings. Once released, the label can be peeled off and residue easily removed with a wet cloth. XD8 label remover is ideal for removing unwanted labels from most containers. Use in factories, processing plants, supermarkets, printing plants and industrial applications. Directions listed to shake can, spray from 15-20 cm liberal, & after allow 5 minutes to soak through and release adhesive. Peel off with hands/scrapper and remove softened adhesive with damp cloth. Cautions use with adequate ventilation, not in confined spaces and get fresh air if required. Misuse by concentrating and inhaling may be fatal. Do not puncture or incinerate even when empty. Keep away from heat, flames, sources of ignition. Propellant hydrocarbon. Warning re fire etc. listed, NZFSA approved non-dairy animal products C101 (incomplete code & means must be use in accordance with special conditions that are specified). Manufacturer contacts found. NZFSA C101-52 means food absent from the room).	SDS (HSNO classification #s & phrases, hazard pictograms, GHS H222 extremely flammable aerosol, H303 may be harmful if swallowed, H313 May be harmful in contact with skin, H333 May be harmful if inhaled. H315 causes skin irritation, H319 causes serious eye irritation, H317 causes allergic skin reaction, H335 may cause respiratory irritation, H336 may cause drowsiness or dizziness, H316 very toxic to aquatics with lengthy effects. Composition d-Limonene, 30-60%, Propylene glycol mono-butyl ether 10-30%, Hydrocarbon propellant 10-30%. Lists. Exposure controls Liquefied petroleum gas TWA 1800 mg/m3. Emergency limits d-Limonene 15-170 ppm, PGMPE 0.93-61 ppm, Hydrocarbon ca 65000-400,000 ppm. Toxicology as per hazards and STOT single exposure and no caution for other / chronic "icity" effects. Environmental effects, Transport requirements. Regulatory includes above & approved handler & tracking requirements).
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Formulation 100% made up of components listed below & FCS contact carryovers per farm model in table		
D-Limonene 1-methyl-4(1-methylethenyl)cyclohexene cine CAS 5989-27-5 from Florida Chemical 45% Raw 1 Solvent (& fragrance).	NICNAS AICS Listings Hazard means secondary notification applies. EPA NZ HSR00xxxx. Recorded as irritant avoid contact/gloves and oxidation CAS 5989-27-5, 5989-54-8, 139-86-3) Limonene & terpineol USFDA21CFR182.60 etc. as a direct flavour w/o excess, other components unfound. NICNAS AICS Listings Hazard means secondary notification applies. EPA NZ HSR00xxxx. Recorded as irritant avoid contact/gloves and oxidation CAS 5989-27-5, 5989-54-8, 139-86-3). FSANZ Food Standards Code direct food ingredient not quickly found. Similarly 21CFR 182.60 direct ingredient not in excess for effect. Over 90% exposure is by flavouring & acute & repeat air limits may be 4500 & 450 microg/m3. d-Limonene is a major constituent of citrus oils, is a monoterpene widely used as a flavour/fragrance additive in cosmetics, foods, and industrial solvents as it possesses a pleasant lemon-like odour. Pub Med d-Limonene has been designated as a chemical with low toxicity based upon lethal dose (LD50) and repeated-dose toxicity studies when administered orally to animals. Food listing/non-toxicity: food listed 21CFR182.60 direct flavouring substance and FSANZ allows permitted synthetic flavourings. Safety Limonene and its oxidation products are skin and respiratory irritants, and limonene-1,2-oxide (formed by aerial oxidation) is a known skin sensitizer. Most reported cases of irritation have involved long-term industrial exposure to the pure compound, e.g., during degreasing or the preparation of paints. However, a study of patients presenting dermatitis showed that 3% were sensitized to limonene.[20].	Although high doses have been shown to cause renal cancer in male rats,[21] limonene is considered by some researchers to be a potential chemo-preventive agent [22] with value as a dietary anti-cancer tool in humans.[23] There is no evidence for carcinogenicity or genotoxicity in humans. The IARC classifies d-limonene as a Group 3 carcinogen: not classifiable as to its carcinogenicity to humans [20][24]. FSANZ Food Standards Code direct food ingredient not quickly found. Similarly 21CFR 182.60 direct ingredient not in excess for effect. Over 90% exposure is by flavouring & acute & repeat air limits may be 4500 & 450 microg/m3. d-Limonene, a major constituent of citrus oils, is a monoterpene widely used as a flavour/fragrance additive in cosmetics, foods, and industrial solvents as it possesses a pleasant lemon-like odour. Abbreviated Lim abstract from Pub Med d-Limonene has been designated as a chemical with low toxicity based upon lethal dose (LD50) and repeated-dose toxicity studies when administered orally to animals. Purity found (physical properties + peroxide 15 (<60) meQ)
Tergitol nonylphenyl ethoxytate CAS 127-87-87-0 NZIoC HSR002725 from Dow Chemical 3.2% previously Ethylene glycol	NZIoC HSR# ok. Bridged between listings USAFDA21CFR178.1010 food contact surface sanitiser not necessarily rinsed or extended to dairy. FSANZ FS Code not found (only alkenyl poly-ethers).	Toxicological information no data to hand for particular target organs. Ecological biodegradable will not accumulate or cause long term problems LC50fathead minnow 3790 mg/L, Daphnia EC50

monobutyl ether CAS 1569-01-3 from Dow Chemical part of 35% components Raw 2 Solvent	Current incomplete ID vs previous concern Chemical study on alkyl-phenols RKZ/2001.029 & note reports show feeding NOAEL 30+ mg/kg, & possible carcinogenicity & endocrine disruption mean an ADI is not set so approval is subject to reviews of this (PAN directory underestimates approvals held as USA only). IMCD MSDS Risk phrases not hazardous no criteria found, safety S23, S24/25 Do not breathe vapours or mists. Avoid contact with skin & eyes.	1812 mg/L. Purity wanted (per column header). Purity found (not found or required for food areas non-contact)
Dowanol PM Propylene glycol methyl ether CAS 111-76-2 from Dow Chemical 18% Raw 3 solvent	NZIoC at 5-10% HSR006398 3.1D 6.1E (dermal) Acutely toxic Flammable Liquids: low hazard USAFDA21CFR 178.1010 food contact surface sanitiser similar, FSANZ 1.3.3.3 GP processing aid, BS 5305, IDF 9101	Side effects appear non-problematic per the food listing, ERMA scope, MSDS and IDF Bulletin 288 on environment & corrosion. Efficacy is according to the food listing above. Purity wanted (per column header). Purity found (not found or required for food areas non-contact)
P48 hydrocarbon propellant LPG liquefied petroleum gas CAS 68476-85-7 HSR001009 was from unfound was from Chevron Phillips 33.8% Hydrocarbon Raw 4 propellant	NZIoC HSR# ok. USA FDA 21 CFR 184.1165 FOUND GRAS with GMP including as an aerating agent, gas, propellant. ACGIH TWA 800 mg/kg. Mildly toxic by inhalation. FSANZ 1.3.1 schedule 5 allows propellants but HC propellant not found - but NZ Food Regulations 1984 - similarly listed Identity and purity of supply propane, butane.	Purity wanted (per column header). Purity found (not found or required for food areas non-contact)
Micro safety per manufacture conditions & while 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

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