

02/06/2020 reference H4337

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To whom it may concern

Special Crème C after work skin conditioner

- Product description: hand treatment (similar)
- Product use: for hands in food areas with incidental food contact

"Passed AsureQuality assessment for food /beverage/ dairy factory to wash hands with incidental food contact" H4337 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 hands in food areas with incidental food contact. Carry-over to food should be minimised to ensure food function or composition are not affected, that residues are within applicable limits and that food legislation requirements are met.
- The assessment is subject to notification of change and expires on 02/06/2025.
- The full report is attached for supplier review and verification. The assessment is activated by countersigning & inclusion of assessment precautions / assessment statement / MPI dairy precautions statement.

Prepared by Global Proficiency for AsureQuality Ltd by
Bob Hutchinson PhD SENIOR DEVELOPMENT SCIENTIST



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: checks (Food Standards Australia-NZ, US FDA 21 CFR/ NSF, Food Chemicals Codex, EPA NZ, EU, French culinary listings or related data for equivalent safety). Background (Australian Accord, 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 and prior assessments (New AsureQuality Assessment. Other skin & manufacture clearances listed in label. Ingredients checked vs cosmetic, NZIoC, AICS).
- Food safety (Is per safety listings or trace level in the table below). Purities (not required or found for low incidental contact). Carry-over (is not expected for low incidental contact).
- QA (Per GMP cert in bulletin summary above).
- QC (chemical safety is per "food safety" above. Microbiological safety is per preservative levels, use instructions and low incidental contact).
- Instructions -Label (Special Crème C after work skin conditioner for very dry skin. Silicone-free skin conditioning cream based on a water-in-oil emulsion moisture and lipids maintains the flexibility and the resistance of the skin. Composition. Used after washing on clean and thoroughly dried skin. Pay particular attention to vulnerable areas such as between the fingers and around the nails. Also for face & avoid eyes. Storage Instructions). Certificate of Dermatological Compatibility certificate is available. Manufactured according to GMP (Good Manufacturing Practice) requirements which include the most recent EU guidelines. Coating Compatibility The Fraunhofer Institute for Manufacturing Engineering and Automation confirms the general coating compatibility of GREVEN® Creme C. WATER, ISOPROPYL PALMITATE ISODODECANE, ISODECYL LAURATE, CERA MICROCRISTALLINA, PARAFFIN, SORBITAN ISOSTEARATE, MAGNESIUM STEARATE, COPERNICA CERIFERA CERA, ALUMINIUM STEARATES, PHENOXYETHANOL, METHYLPARABEN, ETHYLPARABEN, PROPYLPARABEN, BUTYLPARABEN, BHT, FRAGRANCE
- Unwanted effects (Per instructions & clearances above and for ingredients in the table below. Production side effects are not expected per safety listings & extremely low contact).
- Hygiene efficacy (is per claim & certificates above)

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
Severity	Low	Low
Total	Low	Low

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 and prior assessments (New AsureQuality Assessment. Other skin & manufacture clearances listed in label. Ingredients checked vs cosmetic, NZIoC, AICS).

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

(Pryme) Peter Greven Special Crème C after work skin conditioner H4337 28-05-2020	Registrations column. Scope: checks within (NICNAS AICS, FSANZ, US FDA 21 & 40 CFR/ NSF, Food Chemicals Codex, EPA NZ, EU, French culinary listings, WHO or MPI, 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 - Label & bulletin	Label (Special Crème C after work skin conditioner for very dry skin. Silicone-free skin conditioning cream based on a water-in-oil emulsion moisture and lipids maintains the flexibility and the resistance of the skin. Composition. Used after washing on clean and thoroughly dried skin. Pay particular attention to vulnerable areas such as between the fingers and around the nails. Also for face & avoid eyes. Storage Instructions). Certificate of Dermatological Compatibility certificate is available. Manufactured according to GMP (Good Manufacturing Practice) requirements which include the most recent EU guidelines.	Coating Compatibility The Fraunhofer Institute for Manufacturing Engineering and Automation confirms the general coating compatibility of GREVEN® Creme C. WATER, ISOPROPYL PALMITATE ISODODECANE, ISODECYL LAURATE, CERA MICROCRISTALLINA, PARAFFIN, SORBITAN ISOSTEARATE, MAGNESIUM STEARATE, COPERNICA CERIFERA CERA, ALUMINIUM STEARATES, PHENOXYETHANOL, METHYLPARABEN, ETHYLPARABEN, PROPYLPARABEN, BUTYLPARABEN, BHT, FRAGRANCE
HACCP analysis of other aspects	Information and prior assessments (New AsureQuality Assessment. Other skin & manufacture clearances listed in label. Ingredients checked vs cosmetic, NZIoC, AICS). Food safety (Is per safety listings or trace level in the table below). Purities (not required or found for low incidental contact). Carry-over (is not expected for low incidental contact). QA (Per GMP cert in bulletin summary above. QC (chemical safety is per "food safety" above.	Unwanted effects (Per instructions & clearances above and for ingredients in the table below. Production side effects are not expected per safety listings & extremely low contact). Hygiene efficacy (is per claim & certificates above)

	Microbiological safety is per preservative levels, use instructions and low incidental contact)	
Formulation 100% comprises ingredients listed below & carryover nil w/o accidental seepage	Note re all ingredients in formula a Certificate of Dermatological Compatibility certificate which is available.	
Raw 1 ubiquitous	Ubiquitous and safe	
Raw 2 alkyl fatty ester	NZIoC - previous SDS says exempt or complies. EPA cosmetics prohibition section 4 & part 5 CAS unreturned. AICS returned with no 2nd notification required. Fatty alcohol & fatty acid ester returned similar in FSANZ 1.3.3.3 & 21CFR ingredients.	Purity wanted (per column header). Purity found (not required or found in this low incidental contact application)
Raw 3 Paraffinic HC	NZIoC returned for use under appropriate group. AICS returned no 2nd notification required. EPANZ cosmetic standard & restriction unreturned. FSANZ & 21 CFR similar with shorter or longer chains returned	Purity wanted (per column header). Purity found (not required or found in this low incidental contact application)
Raw 4 alkyl fatty ester	Similar material raw 2 had NZIoC - previous SDS says exempt or complies. EPA cosmetics prohibition section 4 & part 5 CAS unreturned. AICS returned with no 2nd notification required. Fatty alcohol & fatty acid ester returned similar in FSANZ 1.3.3.3 & 21CFR ingredients.	Purity wanted (per column header). Purity found (not required or found in this low incidental contact application)
Raw 5 paraffinic HC	AICS returned human health tier 2 with no 2nd notification required. NZIoC single component under appropriate group. EPA cosmetics prohibition section 4 & part 5 CAS unreturned. FSANZ & 21 CFR similar with shorter or longer chains returned	Purity wanted (per column header). Purity found (not required or found in this low incidental contact application)
Raw 6 paraffinic HC	AICS returned human health tier 2 with no 2nd notification required. NZIoC single component under appropriate group. EPA cosmetics prohibition section 4 & part 5 CAS unreturned. FSANZ & 21 CFR similar with shorter or longer chains returned	Purity wanted (per column header). Purity found (not required or found in this low incidental contact application)
Raw 7 fatty acid ester	AICS returned human health tier 2 with no 2nd notification required. NZIoC single component under appropriate group. EPA cosmetics prohibition section 4 & part 5 CAS unreturned. Similar material in FSANZ & 21 CFR direct ingredient lists	Purity wanted (per column header). Purity found (not required or found in this low incidental contact application)
Raw 8 fatty acid salt	AICS returned human health tier 1 with no 2nd notification required. NZIoC single component under appropriate group. EPA cosmetics part 6 colour white w/o restriction. Similar salt components in FSANZ & 21 CFR direct ingredient lists	Purity wanted (per column header). Purity found (not required or found in this low incidental contact application)
Raw 9 wax	AICS human health tier 12 no 2nd notification reqd. Trace w/o concern & cosmetic list unreturned.	Purity wanted (per column header). Purity found (not required or found in this low incidental contact application)
Raw 10 fatty acid salt	AICS no 2nd notification required. Trace w/o concern & cosmetic list unreturned. Similar to raw 8 AICS returned human health tier 1 with no 2nd notification required. NZIoC single component under appropriate group. EPA cosmetics part 6 colour white w/o restriction. Similar salt components in FSANZ & 21 CFR direct ingredient lists	Purity wanted (per column header). Purity found (not required or found in this low incidental contact application)
Raw 11 preservative	EPA NZ cosmetic standard to 1%, under group standard w/o restriction. Similar material has USAFDA21CFR178.1010 food contact surface sanitiser not necessarily rinsed or extended to dairy. ANZFA not found. Chemical study on alkylphenols (relates?) 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?.	EPA NZ HSR003054 HSR006598(dilution) HSR006618(dilution). Purity wanted (see column header). Purity found (N/a for low incidental-nil contact).
Raw 12 preservative	NZIoC & HSR002742 & approved controls. The methyl and propyl esters of parabens are considered GRAS with a maximum total content of 0.1% (21 CFR 184.1490 and 21 CFR 184.1670. Wikipedia Parabens are a class of chemicals widely used as preservatives in the cosmetic and pharmaceutical industries. Parabens are effective preservatives in many types of formulas. These compounds, and their salts, are used primarily for their bactericidal and fungicidal properties.	They can be found in shampoos, commercial moisturizers, shaving gels, personal lubricants, topical/parenteral pharmaceuticals, spray tanning solution, makeup,[1] and toothpaste. They are also used as food additives. Purity wanted (see column header). Purity found (N/a for low incidental-nil contact).
Raw 13 preservative	Similar to raw 12	Similar to raw 12
Raw 14 preservative	Similar to raw 12	Similar to raw 12
Raw 15 preservative	Similar to raw 12	Similar to raw 12
Raw 16 antioxidant	EPA NZ NZIoC HSR002784 NICNAS AICS human health tier 1 no 2nd notification required. FSANZ 1.3.1 sched 2 part 1. 21CFR 78.3570 lubricants with incidental contact found. FDA 21 CFR 172.150 in packaging as antioxidant 0.02% in food fat 0.5 mg/sq m of food contact surface	Purity wanted (per column header). Purity found (not required or found in this low incidental contact application)
Raw 17 perfume trace	Perfume w/o ID trace so w/o concern	Purity wanted (per column header). Purity found (not required or found in this low incidental contact application)
Total 100% (n/a per concentration ranges quoted)		

pH inside growth range & has preservative	pH growth ranges: <i>B. cereus</i> 4.4-9.3, <i>Campylobacter jejuni</i> 4.9-9.0, <i>C. botulinum</i> A & B 4.8-8.5 type E 5-8.5, <i>C. perfringens</i> 5-8.9, <i>Listeria monocytogenes</i> 4.5-8.0, <i>Salmonella</i> 3.8-9.	<i>Staph. aureus</i> 4.3-9.0, <i>vibrio cholerae</i> 6-11, <i>vibrio parahaemolyticus</i> 4.8-9, <i>vibrio vulnificus</i> 5-10, <i>Yersinia enterocolitica</i> 4.4-9.6
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- Food safety (Is per safety listings or trace level in the table below). Purities (not required or found for low incidental contact). Carryover (is not expected for low incidental contact).
- **12 The formulation in confidence follows & is not for public circulation**

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(Pryme) Peter Greven Special Crème C after work skin conditioner H4337 28-05-2020	Registrations column. Scope: checks within (NICNAS AICS, FSANZ, US FDA 21 & 40 CFR/ NSF, Food Chemicals Codex, EPA NZ, EU, French culinary listings, WHO or MPI, 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.
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Formulation 100% comprises ingredients listed below & carryover nil w/o accidental seepage	Note re all ingredients in formula a Certificate of Dermatological Compatibility certificate which is available.	
AQUA CAS 7732-18-5 from - 50-75% Raw 1 ubiquitous	Ubiquitous and safe	
ISOPROPYL PALMITATE CAS 142-91-6 5-10% Raw 2 alkyl fatty ester	NZIoC - previous SDS says exempt or complies. EPA cosmetics prohibition section 4 & part 5 CAS unreturned. AICS returned with no 2nd notification required. Fatty alcohol & fatty acid ester returned similar in FSANZ 1.3.3.3 & 21CFR ingredients.	Purity wanted (per column header). Purity found (not required or found in this low incidental contact application)
ISODODECANE CAS 13475-82-6 5-10% Raw 3 Paraffinic HC	NZIoC returned for use under appropriate group. AICS returned no 2nd notification required. EPANZ cosmetic standard & restriction unreturned. FSANZ & 21 CFR similar with shorter or longer chains returned	Purity wanted (per column header). Purity found (not required or found in this low incidental contact application)
ISODECYL LAURATE CAS 94247-10-6 5-10% Raw 4 alkyl fatty ester	Similar material raw 2 had NZIoC - previous SDS says exempt or complies. EPA cosmetics prohibition section 4 & part 5 CAS unreturned. AICS returned with no 2nd notification required. Fatty alcohol & fatty acid ester returned similar in FSANZ 1.3.3.3 & 21CFR ingredients.	Purity wanted (per column header). Purity found (not required or found in this low incidental contact application)
CERA MICROCRISTALLINA CAS 63231-60-7 1-5% Raw 5 paraffinic HC	AICS returned human health tier 2 with no 2nd notification required. NZIoC single component under appropriate group. EPA cosmetics prohibition section 4 & part 5 CAS unreturned. FSANZ & 21 CFR similar with shorter or longer chains returned	Purity wanted (per column header). Purity found (not required or found in this low incidental contact application)
PARAFFIN CAS 64742-51-4 1-5% HC hydrogenated Raw 6 paraffinic HC	AICS returned human health tier 2 with no 2nd notification required. NZIoC single component under appropriate group. EPA cosmetics prohibition section 4 & part 5 CAS unreturned. FSANZ & 21 CFR similar with shorter or longer chains returned	Purity wanted (per column header). Purity found (not required or found in this low incidental contact application)
SORBITAN ISOSTEARATE CAS 71902-01-7 1-5% Raw 7 fatty acid ester	AICS returned human health tier 2 with no 2nd notification required. NZIoC single component under appropriate group. EPA cosmetics prohibition section 4 & part 5 CAS unreturned. Similar material in FSANZ & 21 CFR direct ingredient lists	Purity wanted (per column header). Purity found (not required or found in this low incidental contact application)
MAGNESIUM STEARATE CAS 557-04-0 1-5% Raw 8 fatty acid salt	AICS returned human health tier 1 with no 2nd notification required. NZIoC single component under appropriate group. EPA cosmetics part 6 colour white w/o restriction. Similar salt components in FSANZ & 21 CFR direct ingredient lists	Purity wanted (per column header). Purity found (not required or found in this low incidental contact application)
Carnauba COPERNICA CERIFERA CERA CAS 8015-86-9 0,1-1% raw 9 wax	AICS human health tier 12 no 2nd notification reqd. Trace w/o concern & cosmetic list unreturned.	Purity wanted (per column header). Purity found (not required or found in this low incidental contact application)
ALUMINIUM STEARATES CAS	AICS no 2nd notification required. Trace w/o concern & cosmetic list unreturned. Similar to raw 8 AICS returned human health tier 1	Purity wanted (per column header). Purity found (not required or found in this low incidental contact application)

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Hamilton

Dear Terry Houlihan,

Please find attached your assessment report for any questions or suggestions and the invoice and later the web listing should follow

Special Crème C after work skin conditioner

- Product description: hand treatment (similar)
- Product use: for hands in food areas with incidental food contact
- Status: passed new AsureQuality assessment factory and related use \$200 + GST for 1:15 hours.

"Passed AsureQuality assessment for food /beverage/ dairy factory to wash hands with incidental food contact" H4337 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 by
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