Restricted Materials Conformity Report

CETR-HAN003.1

Prepared for:	**Hanwha Vision CO., LTD.**
Address:	**-**
Part Name:	**IP Controller(NHP-P400)**
Part/Model/Ref Number:	**-**
Lot Number:	**-**
Samples Received Date:	October 2, 2025
Testing Period:	October 8, 2025 to October 17, 2025
Scopes Included:	California Proposition 65 (The Safe Drinking Water and Toxic Enforcement Act, 1986)
Date of Report:	November 5, 2025

Results

Directive / Regulation	Substance Listing	Conclusions	Substances
Proposition 65	January 2025	Compliant	-

Legend

Compliant:	Compliant for all evaluated substances.
Compliant contingent:	Compliance is contingent upon client addressing identified substances. The action may include a review of risk, application, or use of an applicable declaration/warning.
[Compliant] pending:	[Compliant for most substances.] Ongoing testing/evaluation of identified substances by Claigan is in progress to address remaining risks.
Open risk:	Identified substance risks require client information or feedback to resolve.
Not compliant:	Not compliant for identified substances.
Detected:	Substance was detected, but no regulatory limits in place.
Not detected:	None of the evaluated substances was detected.
Listing Date:	Evaluation includes all associated substances up to and including this date

Revision History

Rev	Description	Written By	Reviewed By	Date
1	Initial Release	Iain Calder	Kirabo Nekesa	November 5, 2025

1 Test Results

Results only apply to the items tested. For additional information on testing and regulatory thresholds, and exemption notation, please see Appendices A and C of this report.

1.1 XRF-ED

1.1.1 General Remarks

1. LOD = limit of detection for that element in that matrix material.
2. The quoted measurement uncertainty represents 2 standard deviations.
3. All measurements were carried out using the Niton® XRF (Appendix **A.2.1**).

1.1.2 Results – Table 1

Sample		Results (ppm)		
Number	Description	Pb	Cd	Hg
95984-1	Box	20 ± 10	<LOD	<LOD
95984-2	Sticker	<LOD	<LOD	<LOD
95984-3	Quick Guide Paper	<LOD	<LOD	<LOD
95984-4	Metal Staple	<LOD	<LOD	<LOD
95984-5	Wiring Guide Paper	<LOD	<LOD	<LOD
95984-6	Safety Paper	<LOD	<LOD	<LOD
95984-7	Bag A	<LOD	<LOD	<LOD
95984-8	Bag B	<LOD	<LOD	<LOD
95984-9	White Foam	<LOD	<LOD	<LOD
95985-1	Torque Key	<LOD	<LOD	<LOD
95985-2	Solder Wire	<LOD	<LOD	<LOD
95989-1	Metal Housing	510 ± 30	<LOD	<LOD
95989-2	Sticker A	<LOD	<LOD	<LOD
95989-3	Sticker Adhesive	<LOD	<LOD	<LOD
95989-4	Barcode Sticker	<LOD	<LOD	<LOD
95989-5	Sticker B	<LOD	<LOD	<LOD
95989-6	Sticker C	<LOD	<LOD	<LOD
95989-7	Light Guide	<LOD	<LOD	<LOD
95989-8	Screw Cover	<LOD	<LOD	<LOD
95989-9	Metal Screw	<LOD	<LOD	<LOD
95989-10	Tech Support Sticker	<LOD	<LOD	<LOD
95989-11	Diagram Sticker	<LOD	<LOD	<LOD
95993-1	Yellow Terminal Block	<LOD	<LOD	<LOD
95993-2	White Terminal Block	<LOD	<LOD	<LOD
95993-3	Green Terminal Block	<LOD	<LOD	<LOD
95993-4	Blue Terminal Block	<LOD	<LOD	<LOD
95993-5	Red Terminal Block	<LOD	<LOD	<LOD
95993-6	Black Terminal Block	<LOD	<LOD	<LOD

Sample		Results (ppm)		
Number	Description	Pb	Cd	Hg
95993-7	Orange Terminal Block	<LOD	<LOD	<LOD
95993-8	Brown Terminal Block	<LOD	<LOD	<LOD
95993-9	Grey Terminal Block	<LOD	<LOD	<LOD
95993-10	Metal Contact	14390 ± 350	<LOD	<LOD
95993-11	Metal Screw A	<LOD	<LOD	<LOD
95993-12	Metal Contact Insert	<LOD	<LOD	<LOD
95993-13	Spring	<LOD	<LOD	<LOD
95993-14	Metal Screw B	<LOD	<LOD	<LOD
95993-15	Metal Screw C	<LOD	<LOD	<LOD
95993-16	Plastic Wire Port Cover	<LOD	<LOD	<LOD
95993-17	Metal Wire Port Cover	920 ± 50	<LOD	<LOD
95994-1	White Switch	<LOD	<LOD	<LOD
95994-2	Metal Ethernet Housing	<LOD	<LOD	<LOD
95994-3	Ethernet Connector	<LOD	<LOD	<LOD
95994-4	Yellow LED	<LOD	<LOD	<LOD
95994-5	Green LED	<LOD	<LOD	<LOD
95994-6	White Plastic Housing	<LOD	<LOD	<LOD
95994-7	Light Guide	<LOD	<LOD	<LOD
95994-8	Info Sticker	<LOD	<LOD	<LOD

1.1.3 Results – Table 2

Sample		Results (ppm)			
Number	Description	Ni	Sb	Br	Cl
95984-1	Box	<LOD	<LOD	<LOD	2796 ± 422
95984-2	Sticker	<LOD	<LOD	<LOD	<LOD
95984-3	Quick Guide Paper	<LOD	<LOD	<LOD	<LOD
95984-4	Metal Staple	<LOD	<LOD	<LOD	N/A
95984-5	Wiring Guide Paper	<LOD	<LOD	11 ± 6	<LOD
95984-6	Safety Paper	<LOD	<LOD	<LOD	<LOD
95984-7	Bag A	<LOD	<LOD	<LOD	<LOD
95984-8	Bag B	<LOD	<LOD	<LOD	<LOD
95984-9	White Foam	<LOD	<LOD	<LOD	1118 ± 533
95985-1	Torque Key	287400 ± 1640	<LOD	<LOD	N/A
95985-2	Solder Wire	<LOD	<LOD	<LOD	N/A
95989-1	Metal Housing	190 ± 60	30 ± 10	<LOD	N/A
95989-2	Sticker A	<LOD	<LOD	<LOD	1412 ± 253
95989-3	Sticker Adhesive	<LOD	<LOD	<LOD	<LOD
95989-4	Barcode Sticker	<LOD	<LOD	<LOD	<LOD
95989-5	Sticker B	<LOD	42 ± 27	<LOD	1887 ± 265
95989-6	Sticker C	<LOD	<LOD	<LOD	1766 ± 287
95989-7	Light Guide	<LOD	<LOD	<LOD	<LOD
95989-8	Screw Cover	<LOD	<LOD	<LOD	<LOD
95989-9	Metal Screw	86640 ± 1250	<LOD	<LOD	N/A
95989-10	Tech Support Sticker	<LOD	<LOD	<LOD	3387 ± 381
95989-11	Diagram Sticker	<LOD	<LOD	<LOD	<LOD
95993-1	Yellow Terminal Block	<LOD	<LOD	4 ± 2	<LOD
95993-2	White Terminal Block	<LOD	<LOD	<LOD	<LOD
95993-3	Green Terminal Block	<LOD	<LOD	143 ± 6	<LOD
95993-4	Blue Terminal Block	112 ± 18	<LOD	4 ± 3	<LOD
95993-5	Red Terminal Block	<LOD	<LOD	17 ± 6	<LOD
95993-6	Black Terminal Block	<LOD	57 ± 27	241 ± 12	<LOD
95993-7	Orange Terminal Block	<LOD	<LOD	22 ± 4	<LOD
95993-8	Brown Terminal Block	<LOD	<LOD	5 ± 3	<LOD
95993-9	Grey Terminal Block	<LOD	57 ± 23	47 ± 5	<LOD
95993-10	Metal Contact	251040 ± 640	120 ± 30	<LOD	N/A
95993-11	Metal Screw A	<LOD	<LOD	80 ± 20	N/A
95993-12	Metal Contact Insert	11240 ± 690	<LOD	<LOD	N/A
95993-13	Spring	88530 ± 1720	<LOD	<LOD	N/A
95993-14	Metal Screw B	88180 ± 1110	<LOD	<LOD	N/A
95993-15	Metal Screw C	561460 ± 1630	<LOD	<LOD	N/A
95993-16	Plastic Wire Port Cover	<LOD	<LOD	<LOD	<LOD
95993-17	Metal Wire Port Cover	410 ± 70	50 ± 10	<LOD	N/A

Sample		Results (ppm)			
Number	Description	Ni	Sb	Br	Cl
95994-1	White Switch	<LOD	<LOD	<LOD	<LOD
95994-2	Metal Ethernet Housing	88800 ± 410	<LOD	<LOD	N/A
95994-3	Ethernet Connector	<LOD	<LOD	108 ± 9	<LOD
95994-4	Yellow LED	457 ± 141	<LOD	<LOD	2252 ± 654
95994-5	Green LED	336 ± 115	<LOD	<LOD	2602 ± 606
95994-6	White Plastic Housing	<LOD	32 ± 15	<LOD	<LOD
95994-7	Light Guide	<LOD	<LOD	<LOD	<LOD
95994-8	Info Sticker	<LOD	<LOD	<LOD	<LOD

NOTE: For these elements and associated substances, risk assessment is carried out by Engineering Analysis.

1.2 Hexavalent Chromium (Cr^{6+}) Screening

Test standards are detailed in Appendix **A.3**.

Sample Number	Sample Description	Result	Conclusion
95984-1	Box	Not detected	Pass
95984-2	Sticker	Not detected	Pass
95984-3	Quick Guide Paper	Not detected	Pass
95984-4	Metal Staple	Not detected	Pass
95984-5	Wiring Guide Paper	Not detected	Pass
95984-6	Safety Paper	Not detected	Pass
95984-7	Bag A	Not detected	Pass
95984-8	Bag B	Not detected	Pass
95984-9	White Foam	Not detected	Pass
95985-1	Torque Key	Not detected	Pass
95985-2	Solder Wire	Not detected	Pass
95989-1	Metal Housing	Not detected	Pass
95989-2	Sticker A	Not detected	Pass
95989-3	Sticker Adhesive	Not detected	Pass
95989-4	Barcode Sticker	Not detected	Pass
95989-5	Sticker B	Not detected	Pass
95989-6	Sticker C	Not detected	Pass
95989-7	Light Guide	Not detected	Pass
95989-8	Screw Cover	Not detected	Pass
95989-9	Metal Screw	Not detected	Pass
95989-10	Tech Support Sticker	Not detected	Pass
95989-11	Diagram Sticker	Not detected	Pass
95993-1	Yellow Terminal Block	Not detected	Pass
95993-2	White Terminal Block	Not detected	Pass
95993-3	Green Terminal Block	Not detected	Pass
95993-4	Blue Terminal Block	Not detected	Pass
95993-5	Red Terminal Block	Not detected	Pass
95993-6	Black Terminal Block	Not detected	Pass
95993-7	Orange Terminal Block	Not detected	Pass
95993-8	Brown Terminal Block	Not detected	Pass
95993-9	Grey Terminal Block	Not detected	Pass
95993-10	Metal Contact	Not detected	Pass
95993-11	Metal Screw A	Not detected	Pass
95993-12	Metal Contact Insert	Not detected	Pass
95993-13	Spring	Not detected	Pass
95993-14	Metal Screw B	Not detected	Pass
95993-15	Metal Screw C	Not detected	Pass
95993-16	Plastic Wire Port Cover	Not detected	Pass

Sample Number	Sample Description	Result	Conclusion
95993-17	Metal Wire Port Cover	Not detected	Pass
95994-1	White Switch	Not detected	Pass
95994-2	Metal Ethernet Housing	Not detected	Pass
95994-3	Ethernet Connector	Not detected	Pass
95994-4	Yellow LED	Not detected	Pass
95994-5	Green LED	Not detected	Pass
95994-6	White Plastic Housing	Not detected	Pass
95994-7	Light Guide	Not detected	Pass
95994-8	Info Sticker	Not detected	Pass

1.3 XRF-WD

1.3.1 General Remarks

1. LOD = limit of detection for that element in that matrix material.
2. The quoted measurement uncertainty represents 2 standard deviation and is calculated using the statistical error of the Poisson distribution.
3. All measurements were carried out using the Bruker® S8 TIGER XRF analyzer (Appendix **A.2.2**).

1.3.2 Results

Sample		Results (ppm)
Number	Description	F
95984-9	White Foam	<LOD

NOTE: For these elements and associated substances, risk assessment is by Engineering Analysis.

1.4 Engineering Analysis

Methodologies are described in Appendix **A.4**.

Sample		Proposition 65	
Number	Description	Risk	Comments
95984-1	Box	Low	
95984-2	Sticker	Low	
95984-3	Quick Guide Paper	Low	
95984-4	Metal Staple	Low	
95984-5	Wiring Guide Paper	Low	
95984-6	Safety Paper	Low	
95984-7	Bag A	Low	
95984-8	Bag B	Low	
95984-9	White Foam	Low	
95985-1	Torque Key	Low	
95985-2	Solder Wire	Low	
95989-1	Metal Housing	Low	
95989-2	Sticker A	Low	
95989-3	Sticker Adhesive	Low	
95989-4	Barcode Sticker	Low	
95989-5	Sticker B	Low	
95989-6	Sticker C	Low	
95989-7	Light Guide	Low	
95989-8	Screw Cover	Low	
95989-9	Metal Screw	Low	
95989-10	Tech Support Sticker	Low	
95989-11	Diagram Sticker	Low	
95993-1	Yellow Terminal Block	Low	
95993-2	White Terminal Block	Low	
95993-3	Green Terminal Block	Low	
95993-4	Blue Terminal Block	Low	
95993-5	Red Terminal Block	Low	
95993-6	Black Terminal Block	Low	
95993-7	Orange Terminal Block	Low	
95993-8	Brown Terminal Block	Low	
95993-9	Grey Terminal Block	Low	
95993-10	Metal Contact	Low	
95993-11	Metal Screw A	Low	
95993-12	Metal Contact Insert	Low	
95993-13	Spring	Low	
95993-14	Metal Screw B	Low	
95993-15	Metal Screw C	Low	

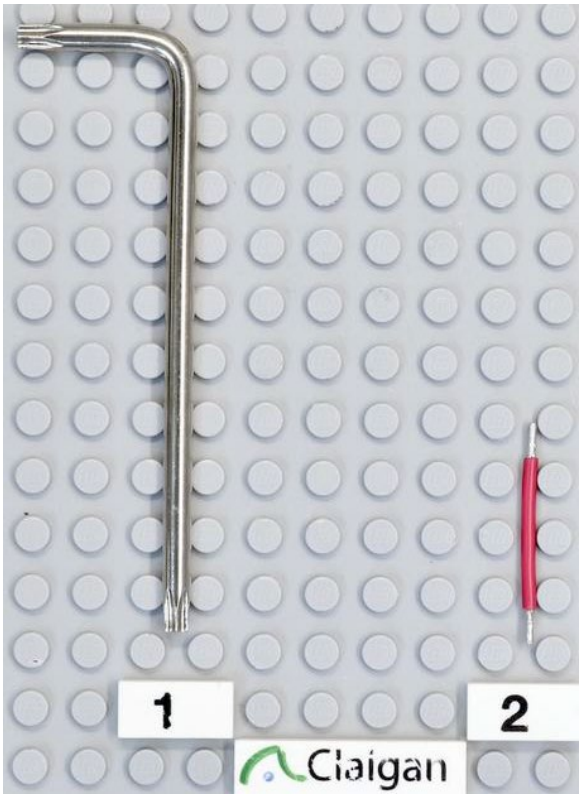
Sample		Proposition 65	
Number	Description	Risk	Comments
95993-16	Plastic Wire Port Cover	Low	
95993-17	Metal Wire Port Cover	Low	
95994-1	White Switch	Low	
95994-2	Metal Ethernet Housing	Low	
95994-3	Ethernet Connector	Low	
95994-4	Yellow LED	Low	
95994-5	Green LED	Low	
95994-6	White Plastic Housing	Low	
95994-7	Light Guide	Low	
95994-8	Info Sticker	Low	

2 Photographs

0414 As received

95983 Exploded view

95984



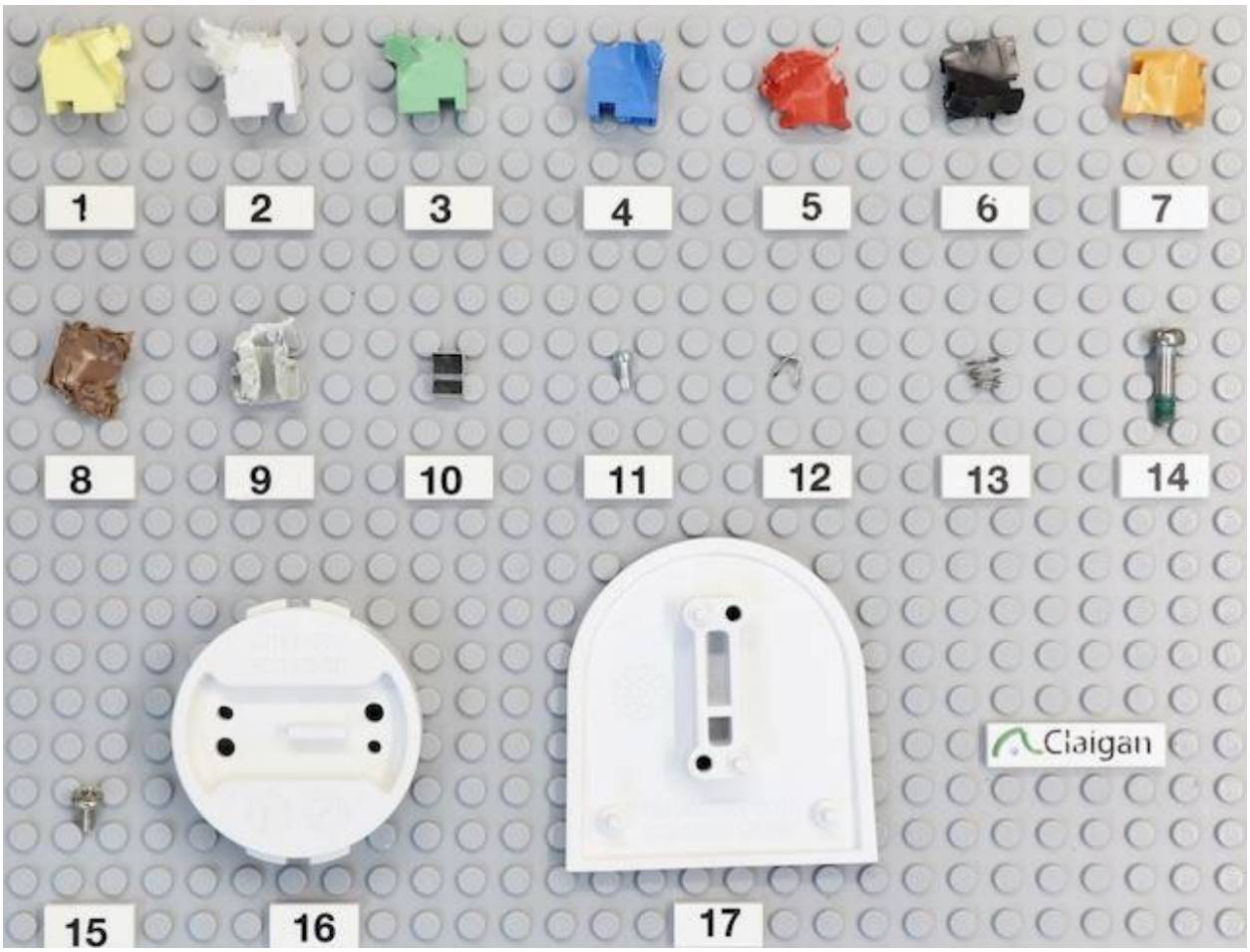
95985

95987 Exploded view

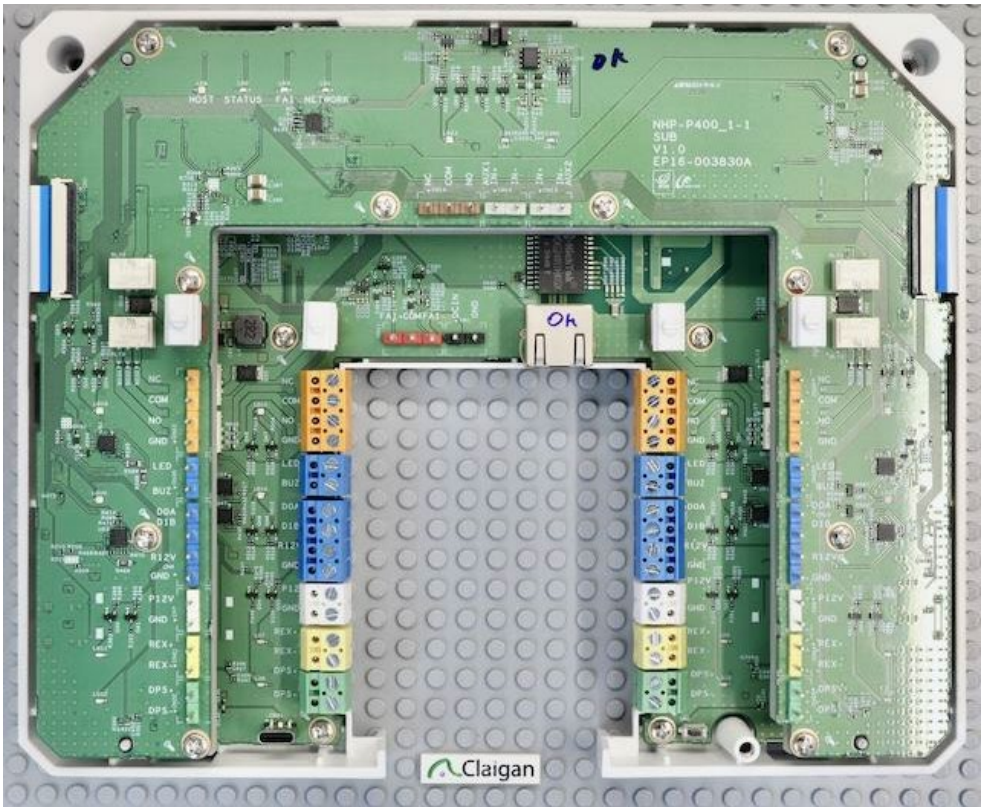
95988 Exploded view

95989

95990 Exploded view

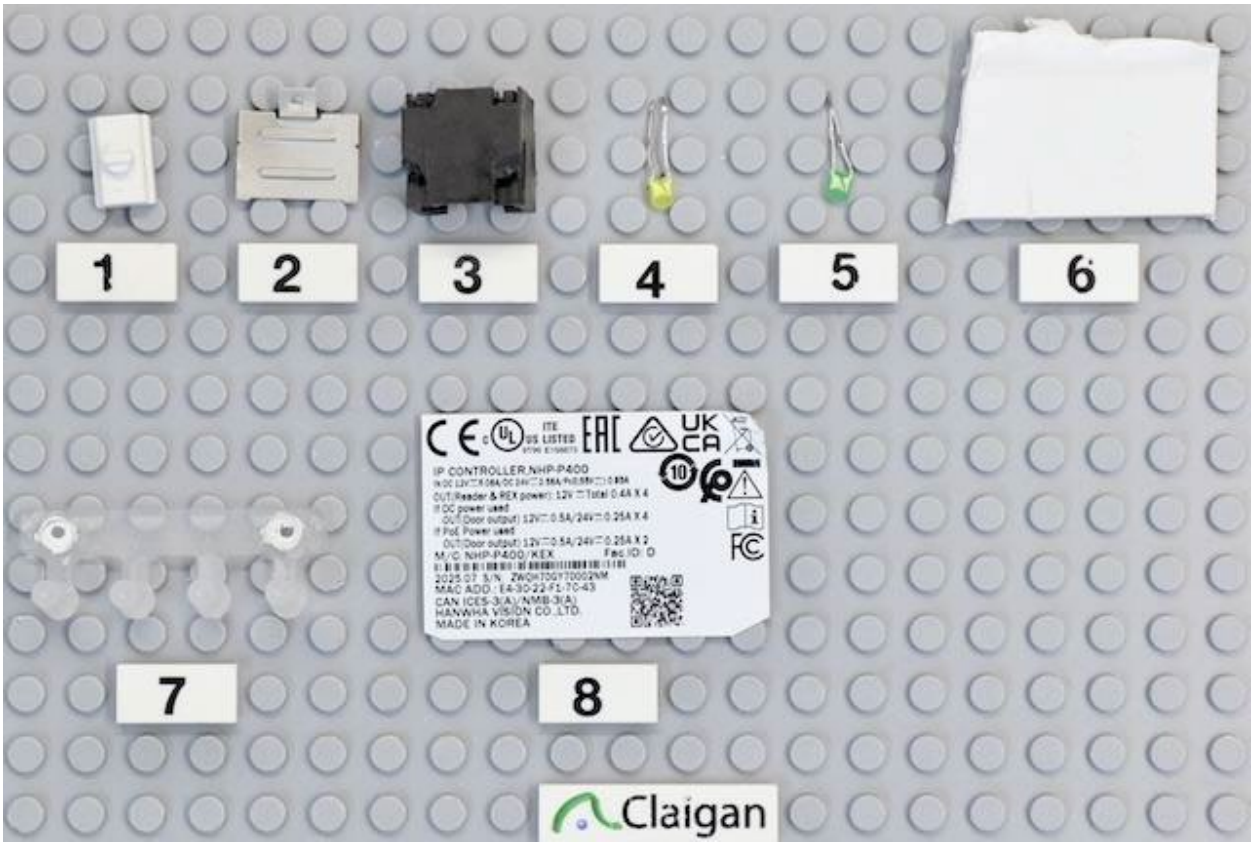


95993



95991 Exploded view

95992 Exploded view



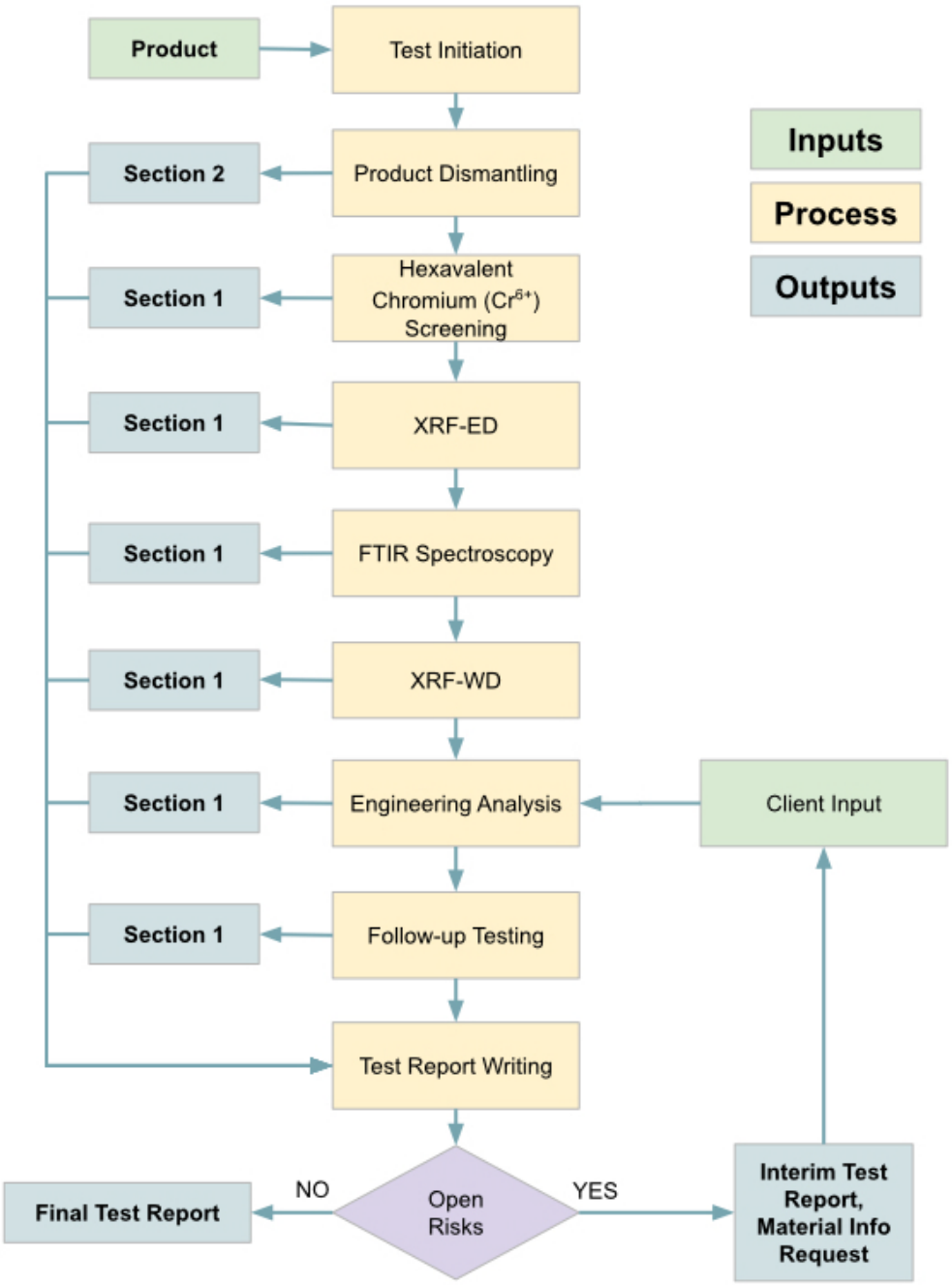
95994

Appendices

Appendix A Test Methodology

Sample preparation follows a version of EN 62321-2 [modified] as referenced in the table in Appendix **A.2**.

A.1 Product Analysis Process Flow Chart



A.2 X-Ray Fluorescence Spectroscopy (XRF)

A.2.1 X-Ray Fluorescence Spectroscopy - Energy Dispersive (XRF-ED)

XRF-ED spectroscopy is carried out with a Niton® XL3t XRF Analyzer made by Thermo Fisher Scientific.

The device directs 50kV x-rays at the target sample. The energy is high enough to eject inner shell electrons from their orbits in individual atoms. The inner shell vacancies are filled by electrons from outer shells, which emit x-ray photons in the process with energies that are characteristic of the particular element (≡ electron shell energy differences). The resulting spectrum is uniquely characteristic of that element and the intensity is calibrated against composition for various surrounding material matrices.

Multiple elements can be detected through deconvolution of the individual spectra by system software. Typical detection limits for various elements in common matrices are shown in the following table[1]:

Element	Polymers (ppm)			Metals (ppm)			
	PE	PVC	PU	Al	Fe	Cu	Sn
Pb	5	15	-	12	60	75	120
Cd	13	15	-	10	25	35	220
Hg	6	30	-	500*	500*	500*	500*
Co	-	-	-	80	1200	75	450
Ni	12	75	-	95	350	175	600
Sb	22	25	-	15	50	60	300
Br	3	8	-	5	20	25	35
Cl	1000	N/A	-	N/A	N/A	N/A	N/A
P	90	250	90	N/A	N/A	N/A	N/A

The XRF analyzer uses direct measurement – no sample preparation is required beyond dismantling the product. All measurements are expressed in ppm: 0.1wt% = 1000ppm = 1000 mg/kg.

NOTE: The LOD for Niton XRF analysis of Cd in Sn metals is 220 ppm, above the 100 ppm regulation limit. However, the Niton XRF analyzer is capable of detecting below 100 ppm at higher measurement error. Any sample with a Cd result of >=50 ppm would be subject to follow up testing with ICP-OES for quantification.

* The LOD for Hg in metal samples is listed as 500 ppm. There are several elements (notably gold (Au), germanium (Ge), and gallium (Ga)) that have characteristic energies that overlap with Hg, and can be misidentified as Hg by the Niton. The Niton XRF analyzer itself contains gold components that can result in interpretation of low levels of Hg for very small samples. For this reason, the LOD for Hg is set as 500 ppm in metal samples, which is below levels of regulatory concern. Resolution of Hg measurements ≥ 500 ppm are verified by spectral review or ICP testing.

Standards for sample preparation and XRF analysis are provided in the following table:

Methods
EN 62321-2 [modified] Determination of certain substances in electrotechnical products. Disassembly, disjointment and mechanical sample preparation
EN 62321-3-1 [modified] Determination of certain substances in electrotechnical products. Screening. Lead, mercury, cadmium, total chromium and total bromine by X-ray fluorescence spectrometry.

A.2.2 X-Ray Fluorescence Spectroscopy - Wavelength Dispersive (XRF-WD)

XRF-WD spectroscopy is carried out with a Bruker® S8 Series 2 TIGER XRF.

The Bruker S8 TIGER is a high-end XRF-WD spectrometer for elemental analysis. The sample is excited with a primary x-ray beam, causing the sample to fluoresce. The primary x-rays eject electrons out of the inner atomic shells (K- and L-shell). The resulting “vacancy” is filled by an electron from an outer atomic shell.

Typical detection limits for various elements in common matrices are shown in the following table:

Element	Bruker S8 Series 2 Polymers (ppm)
F	50

The XRF-WD analyzer uses direct measurement. Sample preparation is limited to containing the sample in the test holder. Samples are measured directly. Very small samples are supported on a metal mesh screen or prolene film. All measurements are expressed in ppm: 0.1%wt% = 1000ppm = 1000 mg/kg.

A.3 Hexavalent Chromium (Cr^{6+}) Screening

The Claigan Chromium TNTplus process with denatured alcohol is a screening process for Cr^{6+}. The modified TNT 854 vial from Hach contains phosphoric acid, acetone, denatured alcohol, and 1,5-diphenylcarbohydrazide.

A colour change (pink) on the swab indicates the presence of hexavalent chromium with a sensitivity of 0.03 µg - comparable to the sensitivity of 0.1 µg reported for the EN/IEC 62321-7-1 test standard.

This is also a direct measurement technique. Using a cotton swab, the chemical is applied directly to the surface of the part under test. Hexavalent chromium is present if a colour change is observed on the swab tip.

A.4 Engineering Analysis

Engineering analysis and risk assessment of the materials found in a product is conducted by:

1. Review of the bill of materials and related documents, if supplied by the client or identified manufacturer(s);
2. Review of XRF screening data;
3. Use of FTIR material information or client-supplied material identification; and/or
4. Triage of high-risk material types based on Claigan document No. RSL-RA-1506B, “Common Locations of Restricted Materials”.

Materials identified as low risk of containing restricted materials do not justify further action. Materials identified as being at high risk of containing restricted materials require additional action to confirm or resolve the risk. Actions may include any of the following steps:

1. Requesting additional material information from the manufacturer;
2. Requesting additional material and/or application information from the client who is requesting assessment;
3. Follow-up testing by GC-MS or ICP-OES, as required.

Restricted substances not listed in Claigan's document No. RSL-RA-1506B are considered to be at low risk of being present in the types of materials used in the applications being reviewed.

Risk assessment is based on information available to Claigan at the time of review and is completed to the best of our knowledge based on the material presented to Claigan, test data, industry standards, supplier data, and available documentation.

A.5 Thermal Desorption Mass Spectroscopy (TD-MS)

TD-MS vaporizes compounds from solid samples and directly measures by mass spectroscopy. The test standard used is IEC-62321-3-4. The substance of interest is vaporized by heating from the sample, ionized by a high voltage needle, moved by nitrogen carrier gas, and measurement by mass spectroscopy.

Substance	Limit of Quantification (LOQ)	Reported Value	Inconclusive Range
DEHP, BBP, DBP, DIBP	500 ppm	ppm	500 to 20,000 ppm
DINP	5000 ppm	ppm	5000 to 20,000 ppm
DIDP	5000 ppm	ppm	≥ 5000 ppm
DecaBDE, NonaBDE	500 ppm	Inconclusive	≥ 500 ppm
TBBPA	500 ppm	Inconclusive	≥ 500 ppm
TPP	500 ppm	Inconclusive / >1000 ppm	≥ 500 ppm
D6	500 ppm	Inconclusive	≥ 500 ppm
NMP	500 ppm	Inconclusive / >1000 ppm	≥ 500 ppm
UV Stabilizers (as defined in Appendix B)	500 ppm	Inconclusive / >1000 ppm	≥ 500 ppm (per substance)

Any result below the LOQ is reported as ND. Errors on reported values are ± 30%. Results in the inconclusive range for all substances require follow up testing by GC-MS using the appropriate testing standard.

Substance	Reference
DEHP, BBP, DBP, DIBP	EN/IEC 62321-3-4: Phthalates in Polymers by Thermal Desorption Mass Spectrometry (TD-MS)
DINP, DIDP, DecaBDE, NonaBDE, TBBPA, TPP, D6, UV Stabilizers, NMP	EN/IEC 62321-3-4: Phthalates in Polymers by Thermal Desorption Mass Spectrometry (TD-MS) [modified]

Due to the relationship between SCCP's, MCCP's, BPA, and orthophthalates, SCCP's, MCCP's, and BPA would generally be seen as low risk if high concentrations of orthophthalates are not expected to be present.

Polybrominated biphenyl ethers found in physical products are degradation products from nonaBDE or decaBDE. NonaBDE and decaBDE are tested to determine if any PBDE are likely present. If neither are present, the lower molecular weight PBDE would not be present.

The TD-MS testing for NMP, PBB/PBDE, tetrabromobisphenol A (TBBPA), TPP, UV stabilizers, and siloxanes (D6) is for the presence of each respective chemical structure. Many brominated flame retardants are TBBPA-based (such as tetrabromobisphenol A diglycidyl ether) but are not the regulated substance TBBPA. Likewise, many phosphated flame retardants contain chemical structures similar to TPP, but are not the regulated substance TPP. A result of "not detected" for TPP also implies that PIP 3:1 is not

present. D6 is the highest concentration siloxane in silicone and is used as the reference substance for the presence of any regulated siloxane (D4, D5, D6, and L3). UV stabilizers are listed as “inconclusive” when one or more of the UV stabilizers being identified is above the inconclusive range. For inconclusive results at TD-MS, further testing by GC-MS is required to confirm whether the substance identified is NMP, PBB/PBDE, TBBPA, TPP, UV stabilizers or D4/D5/D6/L3, respectively.

A.6 Gas/Liquid Chromatography Mass Spectroscopy (GC-MS, LC-MS)

Gas/Liquid Chromatography Mass Spectroscopy (GC/LC-MS) combines the two analytical techniques of chromatography (the physical separation of chemical components) and mass spectroscopy (MS) to obtain a quantitative analysis of chemical components in a substance. GC distinguishes chemical components by their diffusion time through a capillary while LC uses conventional chromatography which separates components through the combined actions of hydrophilic and hydrophobic solvents in a column. The MS stage measures the mass to charge ratio of the components (fragments in the case of GC) as they emerge from the chromatography column and are ionized. Together they unambiguously identify chemical presence and concentration. Typical sensitivity is 1pg of target[2]. This translates into ppb even for very small samples although routine measurements are usually limited to ppm. Measurements are based on a combination of parameters (including material composition) and calibrations. Values provided should be seen as representative of the order of magnitude of the quantity and not taken as an absolute value.

In absence of specific test standard for the regulated substance, samples are prepared by undergoing extraction by appropriate methods or general standards for the substance, substrate and exposure modelling.

Reference standards are listed in the following table:

Substance	Reference
PBB/PBDE	EN/IEC 62321-6: Polybrominated Biphenyls and Polybrominated Diphenyl Ethers in Polymers by Gas Chromatography Mass Spectrometry (GC-MS)
Phthalates	EN/IEC 62321-8: Phthalates in Polymers by Gas Chromatography Mass Spectrometry (GC-MS)
PAH’s	AfPS GS 2019:01 PAK (Germany): Measurement of PAH’s by GC-MS
Azocolourants	EN 14362-1: Measurement of Azocolourants by GC-MS
Organotins	ISO 17353: Determination of selected organotin compounds
PFAS	EN 17681-1: Organic fluorine: Determination of non-volatile compounds by extraction method using liquid chromatography
SCCP’s	ISO 18219: Leather – Determination of chlorinated hydrocarbons in leather (SCCP’s)

A.7 Inductively Coupled Plasma Optical Emission Spectroscopy (ICP-OES)

An inductively coupled plasma (ICP) is a high-density plasma generated in a low-pressure gas through the action of an oscillating magnetic field. The ions in the plasma can then be analyzed spectroscopically by their optical emission (OES, sometimes known as atomic emission spectroscopy - AES). ICP-OES uses the inductively coupled plasma to ionize material from a sample that has been dissolved in an appropriate solvent and sprayed into the plasma. Then optical emission spectroscopy is used to obtain a quantitative analysis of chemical components in a substance. The sensitivity of ICP-OES is typically around 5ppm. All elements can be quantified by ICP-OES except C, H, O, N (components of the solvent), and the halogens.

The standard EN/IEC 62321-1:2013 declares that ICP-OES is a follow-up method for XRF and provides a definitive test. Therefore, in cases where the XRF results are inconclusive, ICP-OES is employed.

For EU REACH nickel restriction and Proposition 65 metal exposure risks, metal release rate is measured rather than metal content. For these test methods, ICP-OES is used as the analytical method to measure the amount of metal migrating into solution or wetted wipe.

Reference standards are listed in the following table:

Substance	Reference
Hg	EN/IEC 62321-4: Mercury in Polymers, Metals and Electronics by CV-AAS, CV-AFS, ICP-OES and ICP-MS
Cd, Pb, Cr (plus all other metals)	EN/IEC 62321-5: Cadmium, Lead and Chromium in Polymers and Electronics and Cadmium and Lead in Metals by AAS, AFS, ICP-OES and ICP-MS

A.8 Combustion Ion Chromatography (CIC)

An absorbent solution is added to the combustion bomb. The sample is weighed and placed in a cup in the bomb, which is then filled with oxygen and ignited and left at room temperature. The cup is rinsed with an absorbent solution and mixed with the rest of the absorbent solution in the bomb, then transferred to a volumetric flask where the remaining volume is filled with deionized water. The solution is filtered and poured into a vial for analysis by ion chromatography, which, like liquid chromatography, separates the different ions in the solution based on the interactions between the ions and the resin within the columns through which the solution is pushed. The resulting chromatograph is analyzed to determine the concentrations of the ions in solution. This method is used to measure the concentrations of sulphur and halogens in a sample.

Substance	Reference
Br, Cl, P, F, I, S	EN 14582: Characterization of waste - Halogen and sulfur content - Oxygen combustion in closed systems and determination methods

A.9 EN 1811 and EN 12472

For EU nickel testing standards (EN 1811:2011 + A1:2015, EN 12472:2020) the sample is first placed in an artificial sweat solution for one week before testing and then the solution is tested, not the original object. Analytical testing employs ICP-OES as described in Appendix **A.7**. Three distinct measurements are required by EU Standard EN 1811. EN 1811 alone is applied to nickel-containing material that is not coated with a functional barrier. Standard EN 12472 is applied to samples that include a coating over the nickel-containing material and refers to EN 1811 as the method of nickel release analysis following the specified wear and corrosion simulation. The detection limit of this method is 0.05 µg/cm^2/week.

The compliance limit for EN 1811 is defined as:

Substance	Condition	Pass threshold for detected substance (µg/cm^2/week)
Ni	Articles with a REACH Article 67 migration limit of 0.5 µg/cm^2/week	<0.88
Ni	Articles with a REACH Article 67 migration limit of 0.2 µg/cm^2/week	<0.35

A.10 Surface Wipe Test

A variation on this procedure is described in NIOSH Method 9100: Lead in Surface Wipe Samples, and is designed to simulate transmission of Pb, or other substances, at risk of being released onto hands by touching an object and subsequently ingested. In this method disposable wipes are moistened with a

wetting agent (distilled water or other appropriate solvent) and then used to wipe the object under test thoroughly. The wipe is then analyzed by ICP-OES or GC-MS, depending on the substance under consideration, to determine the amount of the substance removed during the wiping process. Based on legal settlements and correlation to Pb safe harbour limits, the following limits have been applied to NIOSH 9100 results with respect to Proposition 65 for standard occasional contact situations:

Substance	Condition	Pass threshold for detected substance (µg)
Pb	Standard occasional contact	<1
Cd	Standard occasional contact	<8
As	Standard occasional contact	<20
Cr	Standard occasional contact	<16
Others	Standard occasional contact	ND

A.11 Fourier Transform Infrared Spectroscopy (FTIR)

FTIR measures the absorption of light over the near infrared spectrum (wavelengths of several µm's or wavenumbers of 1000's of cm^{-1}). Absorption takes place from molecular modes of excitation so that a spectrum can provide a fingerprint of specific compounds, when calibrated against known standards. The name of the technique arises because scanning is not over wavelength directly, but over the position of a Michelson interferometer mirror, and then the resulting output of absorption vs. position is Fourier transformed to a spectrum of absorption vs. wavelength (more commonly wavenumber = $wavelength^{-1}$). The detailed procedure is as follows:

> Claigan reviews peaks in ranges from 1774-1784 cm^{-1} and 1521-1535 cm^{-1} for possible melamine risks. Samples with peaks identified in both ranges (double-peaked) are marked as "yes". Otherwise, the sample is marked as "no".

A.12 Ultraviolet-Visible Spectrophotometry (UV-Vis)

In cases where quantitative results are required for hexavalent chromium testing, additional testing can take place according to test standard EN/IEC 62321-7-1 (protective coatings) or EN/IEC 62321-7-2 (polymers and electronics).

For EN/IEC 62321-7-1 the sample is placed in boiling water for a fixed period of time to extract Cr. Then the resulting solution is subjected to UV-Vis spectrophotometry, which determines the concentration of Cr^{6+} from its characteristic absorption spectrum. The lower limit on sensitivity by this method is 0.1 $\mu g/cm^2$. Knowledge of the thickness of the plating can be used to calculate the concentration.

If the sample is covered by a polymer coating, then an acetone-based solvent (similar to the Hexavalent Chromium (Cr^{6+}) Screening process solvent) can be used first to remove the polymer. This procedure is suggested by EN/IEC 62321-7-1 in the case of coated surfaces, but it is not part of the official test.

For EN/IEC 62321-7-2 the sample is placed in an organic solvent to prepare the material, followed by an alkaline digestion procedure to extract the Cr^{6+}. Then the analysis proceeds as for EN/IEC 62321-7-1.

Note that a qualitative (visual) determination of the presence of Cr^{6+} can also be performed by adding a Cr^{6+} sensitive dye to the solution. The dye is 1,5-diphenylcarbazide, the same dye used with the Hexavalent Chromium (Cr^{6+}) Screening process.

When the test sample is leather, then ISO standard 17075-1 is followed. In this method 22.8g of $K_2HPO_4{:}3H_2O$ is dissolved in 1 litre of water and adjusted to a pH of 8.0 ± 0.1 with phosphoric acid, followed by degassing with argon or nitrogen. Next the sample undergoes mechanical agitation in the solution before examination by UV-Vis.

Standard	Sample Type	Threshold
EN/IEC 62321-7-1	Coatings	>0.13 µg/cm^2 is a positive result
EN/IEC 62321-7-2	Polymers, Electronics	>0.13 µg/cm^2 is a positive result
ISO 17075-1	Leather	<3 mg/kg is compliant with REACH Article 67 restrictions

A.13 Asbestos Testing

Asbestos testing is generally carried out without sample preparation and follows US EPA Method 600 R-93/116: Asbestos. The material is observed in a stereomicroscope and, if in the form of fibres, it is transferred to a polarized light microscope (PLM) where the concentration of fibrous asbestos is determined by counting or quantified area determination. For material found to be in powder form, the sample is transferred to a transmission electron microscope (TEM) where counting, area determination, electron diffraction, and/or energy dispersive x-ray analysis is carried out. The detection limit is 0.5%.

Appendix B Substance Families

Families of related substances are often tested together, especially in GC/LC-MS. These families are identified in an abbreviated form in the applicable test section. The complete families are listed in this appendix.

Family Name	Family Members	Substances Often Tested Individually	Short Form
Polybrominated Biphenyls	Monobrominated Biphenyls (MonoBB) Dibrominated Biphenyls (DiBB) Tribrominated Biphenyls (TriBB) Tetrabrominated Biphenyls (TetraBB) Pentabrominated Biphenyls (PentaBB) Hexabrominated Biphenyls (HexaBB) Heptabrominated Biphenyls (HeptaBB) Octabrominated Biphenyls (OctaBB) Nonabrominated Biphenyls (NonaBB) Decabrominated Biphenyl (DecaBB)	None	PBB's
Polybrominated Diphenyl Ethers	Monobrominated Diphenyl Ethers (MonoBDE) Dibrominated Diphenyl Ethers (DiBDE) Tribrominated Diphenyl Ethers (TriBDE) Tetrabrominated Diphenyl Ethers (TetraBDE) Pentabrominated Diphenyl Ethers (PentaBDE) Hexabrominated Diphenyl Ethers (HexaBDE) Heptabrominated Diphenyl Ethers (HeptaBDE) Octabrominated Diphenyl Ethers (OctaBDE) Nonabrominated Diphenyl Ethers (NonaBDE) Decabrominated Diphenyl Ethers (DecaBDE)	DecaBDE	PBDE's
Group 1 Phthalates[1]	Di(2-ethylhexyl) Phthalate (DEHP) Dibutyl Phthalate (DBP) Benzyl Butyl Phthalate (BBP) Di-(Iso-Butyl) Phthalate (DIBP) Di-(Iso-Nonyl) Phthalate (DINP) Di-(Iso-Decyl) Phthalate (DIDP)	DEHP	Group 1 Phthalates
Group 2 Phthalates	Di(2-methoxyethyl) phthalate (DMEP) Dipentyl phthalate (DPP) Di-(Iso-Hexyl) Phthalate (DIHxP) Di-(Iso-Pentyl) Phthalate (DIPP) Di-(Iso-Octyl) Phthalate (DIOP) Di-(N-Hexyl) Phthalate (DNHP) 1,2-Benzenedicarboxylic acid, di-C6-8-branched alkylesters, C7-rich (DIHP) 1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkylesters (DHNUP) N-pentyl-isopentyl phthalate (PIPP) Dicyclohexyl phthalate (DCHP)	None	Group 2 Phthalates
Short Chain Chlorinated Paraffins	C10-C13	None	SCCP's
Medium Chain Chlorinated Paraffins	C14-C17	None	MCCP's
Polycyclic Aromatic Hydrocarbons[2]	Acenaphthene Acenaphthylene Anthracene	None	PAH's

Family Name	Family Members	Substances Often Tested Individually	Short Form
Polycyclic Aromatic Hydrocarbons (continued)[2]	Benzo[a]anthracene Benzo[b]fluoranthene Benzo[j]fluoranthene Benzo[k]fluoranthene Benzo[g,h,i]perylene Benzo[a]pyrene Benzo[e]pyrene Benzo[rst]pentaphene Dibenzo[a,h]anthracene Dibenzo[a,h]pyrene Dibenzo[a,l]pyrene Dibenzothiophene Chrysene Fluoranthene Fluorene Indeno[1,2,3-c,d]pyrene Naphthalene Perylene Phenanthrene Pyrene	None	PAH's (continued)
Azocolourants	4-Aminodiphenyl Benzidine 4-Chloro-o-toluidine 2-Naphthylamine o-Aminoazotoluene 2-Amino-4-nitrotoluene p-Chloroaniline 2,4-Diaminoanisole 4,4'-Diaminodiphenylmethane 3,3'-Dichlorobenzidine 3,3'-Dimethoxybenzidine 3,3'-Dimethylbenzidine 3,3'-Dimethyl-4,4'-diamino diphenylmethane p-Cresidine 4,4'-Methylene-bis-(2-chloroaniline) 4,4'-Oxydianiline 4,4'-Thiodianiline o-Toluidine 2,4-Toluylendiamine 2,4,5-Trimethylaniline o-Anisidine 4-Aminoazobenzene 2,4-Xylidine 2,6-Xylidine	None	Azocolourants
UV Stabilizers	UV320 UV326 UV327 UV328 UV329 UV350	None	UV Stabilizers
Perfluoroalkyl Carboxylates	Perfluoro-butanoic acid (PFBA) Perfluoro-pentanoic acid (PFPeA) Perfluoro-hexanoic acid (PFHxA) Perfluoro-heptanoic acid (PFHpA)	PFOA/PFNA, LC-PFAC	P26

Family Name	Family Members	Substances Often Tested Individually	Short Form
Perfluoroalkyl Carboxylates (continued)	Perfluoro-dodecanoic acid (PFDoA) Perfluoro-tridecanoic acid (PFTrDA) Perfluoro-tetradecanoic acid (PFTeDA) Perfluoro-3-7-dimethyl octane-carboxylate (PF-3,7 DMOA) 7H-Dodecafluoro heptane carboxylate (HPFHpA) 2H,2H-Perfluoro decan carboxylate (H2PFDA) 2H,2H,3H,3H-Perfluoro-undecanoicacid (4HPFUnA) Methyl perfluorooctanoate (Me-PFOA) Ethyl perfluorooctanoate (Et-PFOA) 1H,1H,2H,2H-Perfluorooctyl acrylate (6:2 FTA) 1H,1H,2H,2H-Perfluorodecyl acrylate (8:2 FTA) 1H,1H,2H,2H-Perfluorododecyl acrylate (10:2 FTA) 1H,1H,2H,2H-Perfluorohexanol (4:2 FTOH) 1H,1H,2H,2H-Perfluorooctanol (6:2 FTOH) 1H,1H,2H,2H-Perfluorodecanol (8:2 FTOH) 1H,1H,2H,2H-Perfluorododecanol (10:2 FTOH) 1H,1H,2H,2H-Perfluorodecyl methacrylate (8:2 FTMA) Hexafluoropropylene oxide dimer acid (HFPO-DA)	PFOA/PFNA, LC-PFAC	P26 (continued)
Perfluoroalkyl Sulfonates	Perfluoro-octane-sulfonic acid (PFOS) Perfluoro-octane-sulfon-amide (PFOSA) N-Methyl-perfluoro-octane-sulfon-amide (N-Me-FOSA) N-Ethyl-perfluoro-octane-sulfon-amide (N-Et-FOSA) N-Methyl-perfluoro-octane-sulfon-amido-ethanol (N-Me-FOSE) N-Ethyl-Perfluoro-octane-sulfon-amido-ethanol (N-Et-FOSE) Perfluoro-butane-sulfonic acid (PFBS) Perfluoro-hexane-sulfonic acid (PFHxS) Perfluoro-heptane-sulfonic acid (PFHpS) Perfluor-decane-sulfonic acid (PFDS) 1H,1H,2H,2H-Perfluorooctane-sulphonic acid (6:2FTS) 1H,1H,2H,2H-Perfluorodecane sulphonic acid (8:2 FTS) Perfluoro-1-octanesulfonyl fluoride (POSF)	PFOS	P13
Siloxanes	D4 D5 D6 L3 L4	None	Siloxanes
Organotin Compounds	Tributyltin (TBT) including TBTO Triphenyltin (TPT) Dioctyltin (DOT) Dibutyltin (DBT) Methyltin (MeT) Dimethyltin (DMT) Trimethyltin (TriMT) Dipropyltin (DProT) Tripropyl tin (TPrT, TPT) Monobutyltin (MBT) Tetrabutyltin (TeBT) Monooctyltin (MOT) Trioctyltin (TOT) Diphenyltin (DPhT) Tricyclohexyltin (TcyT) Monophenyltin (MphT) Tetraoctyltin (TeOT) Tetraethyltin(TeET)	DOT/MOT	Organotins

[1] Of the Group 1 phthalates, only DEHP, DBP, BBP, and DIBP are in scope of RoHS. DINP and DIDP are only in scope of Proposition 65 while DIBP is not in scope of Proposition 65.

[2] Of the polycyclic aromatic hydrocarbons (PAH's), dibenzo[a,h]pyrene and dibenzo[a,l]pyrene are only in scope for MDR section 10.4.1.

Appendix C Notes on Regulations

C.1 Notes Regarding RoHS

C.1.1 RoHS 2 (Directive 2011/65/EU)

Assessment of compliance for RoHS restricted substances (Pb, Hg, Cd, Cr^{6+}, PBBs and PBDEs) is based on the risk-based approach of the EN/IEC 62321 standards. The EN/IEC 62321 standards are not comprehensive for all situations, rely partially on risk-based judgment, and have the opportunity for error. Claigan follows the EN/IEC 62321 standards for conformity assessment in good faith; however, the client should be aware that these standards have the opportunity for error.

Claigan's application of EN/IEC 62321-2 (disassembly, disjointment, and mechanical sample preparation) involves complicated processes regarding the handling of single and composite materials. Although error is minimized with the use of controls, validation, methodology, and best efforts, no disassembly process is immune to the possibility of missing or misinterpreting a result.

The risk-based approach extends to the sampling of brominated materials for assessment of the risk of PBB/PBDE content. Samples selected for follow up testing by GC-MS are representative of the types of materials that are identified as risks for PBB/PBDE content following XRF screening, and of sufficient sample size to obtain conclusive PBB/PBDE detection by GC-MS testing. Sample materials with XRF screening results that indicate less than 1500 ppm of Br or Sb present are not considered likely to contain PBB or PBDE as a flame retardant.

For RoHS, Pass/Inconclusive/FAIL are defined in the following table:

RoHS XRF Thresholds

Elements	Regulated Limit	Pass*	Inconclusive *,†	FAIL*
Pb	1000 ppm	<700 ppm	700 ppm ≤ [Pb] ≤ 1300 ppm	>1300 ppm
Cd	100 ppm	<70 ppm	70 ppm ≤ [Cd] ≤ 130 ppm	>130 ppm
Hg	1000 ppm	<700 ppm	700 ppm ≤ [Hg] ≤ 1300 ppm	>1300 ppm

* Unless a valid exemption applies or composite material is evaluated, in which case testing proceeds according to the Claigan Sample Testing process.

† Inconclusive results for RoHS thresholds for Pb, Cd and Hg are generally resolved by ICP-OES.

Samples that include a coating may need to be scored to obtain accurate readings for both the coating and the substrate in the event that the initial combined XRF scan determines a restricted material is present at an inconclusive level. Both the coating and the substrate are each considered a homogeneous material and individually must be RoHS compliant. The sample is evaluated before and after mechanical removal (scoring) of the surface coating.

In these cases, the suffixes "a" and "b" are added to the end of the sample numbers. The "a" sample represents the initial XRF reading, while the "b" sample represents the scored sample. A single conclusion is provided for the two XRF readings combined as they represent a single component. The sample will be marked pass or pass with an exemption if the readings demonstrate an allowable concentration of the restricted material is present in the sample coating and substrate. However, if the scoring process determines that the restricted material is present in the coating and not in the substrate, then the sample will be marked as a fail. This can even occur when the reading of the restricted material is less than 1000 ppm (or 100 in the case of Cd) because the measurement from the coating will always be proportionally reduced by the presence of the substrate.

Legend for Pass by Exemption (for indicative use):

6a: RoHS Exemption III 6(a): Pb in steel up to 3500 ppm (0.35%) for machining purposes and in galvanised steel.

6a1: RoHS Exemption III 6(a)-I: Pb in steel up to 3500 ppm (0.35%) for machining purposes and in galvanised steel and in batch hot dip galvanised steel up to 2000 ppm (0.2%).

6b: RoHS Exemption III 6(b): Pb in aluminum up to 4000 ppm (0.4%).

6b1: RoHS Exemption III 6(b)-I: Pb in aluminum up to 4000 ppm (0.4%), provided it stems from lead-bearing aluminum scrap recycling

6b2: RoHS Exemption III 6(b)-2: Pb in aluminum up to 4000 ppm (0.4%) for machining purposes.

6c: RoHS Exemption III 6(c): Pb in copper alloy up to 40,000 ppm (4%).

7a: RoHS Exemption III 7(a): Pb in high temperature solder (>85% Pb).

7c1: RoHS Exemption III 7(c)-I: Electrical and electronic components containing Pb in a glass or ceramic other than dielectric ceramic in capacitors.

7c2: RoHS Exemption III 7(c)-II: Pb in high voltage ceramic capacitors.

8b: RoHS Exemption III 8(b): Cd and its compounds in electrical contacts.

8b1: Cadmium and its compounds in electrical contacts in specific applications

15: Lead in solders to complete a viable electrical connection between semiconductor die and carrier within integrated circuit flip chip packages

15a: Lead in solders to complete a viable electrical connection between the semiconductor die and carrier within integrated circuit flip chip packages where at least one of the specifying criteria apply

For official versions and details of exemptions see EU Commission text at https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32011L0065.

C.1.2 RoHS 3 (Directive 2015/863)

Assessment of compliance for RoHS restricted substances is based on the risk-based approach of the EN/IEC 62321 standards. Under RoHS 3, four phthalates (DEHP, DIBP, DBP and BBP) are restricted in homogenous materials at 1000 ppm. Even with the best of processes, validations, and techniques, the disassembly process according to EN/IEC 62321-2 may not identify every potential instance of risk of phthalates. Very small or thin materials, such as glues or adhesives, may not always be identified for phthalate risk. Claigan will ensure best efforts are made to identify risk; however, there are currently no 100% effective methods for extremely small amounts of phthalates.

C.2 Notes Regarding REACH

C.2.1 REACH Article 33 Communication Requirements

REACH Substances of Very High Concern (SVHCs) are reportable if present in an article above 0.1% w/w. An article is defined by the Court of Justice of the European Union Case C-106/14. The Candidate List of SVHCs is updated approximately biannually. The samples reviewed in this test report for SVHCs were reviewed to the list of substances valid as of the effective date noted in the preamble of the report.

Compliance for REACH SVHC's is a risk-based assessment based on engineering review, screening testing, and in-depth testing of high-risk materials. The evaluation is structured to include all major applicable REACH SVHC's, with a focus on substances included in industry declarations for applicable products. Because of the large number of REACH SVHC's, errors and gaps in knowledge in the supply chain, and potential unknown uses of some REACH SVHC's, there is opportunity for a substance to be omitted from the review.

When DEHP is detected below a concentration of 10,000 ppm in PVC, concentrations of BPA are not expected to exceed 1000 ppm. In these cases, the BPA risk is considered to be resolved.

When Group 1 phthalates are detected below a concentration of 10,000 ppm in PVC, concentrations of SCCP's/MCCP's are not expected to exceed 1000 ppm. In these cases, the SCCP's/MCCP's risks are considered to be resolved. Similarly, there is only a risk of a material containing L3 if that sample contains greater than 1000 ppm D6.

DOTE, DOTE/MOTE, and DOTL (dioctyltin dilaurate) are calculated based on the measured quantity of DOT (dioctyltin). Due to derivatization, only DOT is directly measurable.

In the case of grouped samples yielding a result of 700-999 ppm of a SVHC, the samples will receive a "compliant contingent" conclusion as it is likely one or more samples exceed 1000 ppm concentration.

C.2.2 REACH Article 67 Restrictions

REACH restrictions are imposed for specific substance and specific use scenarios. Restriction thresholds vary by application. Samples are reviewed for REACH restrictions based on XRF identification of substances, Engineering Analysis, and application information disclosed by the client. The samples are evaluated to the REACH Restrictions current as of the date of testing, unless otherwise specified.

C.2.2.1 REACH Restriction, Annex XVII, Entry 68

With respect to: linear and branched perfluorocarboxylic acids of the formula CnF2n+1-C(=O)OH where n=8, 9, 10, 11, 12, or 13 (C9-C14 PFCAs) including their salts, and any combinations thereof.

The term LC-PFAC refers to the long-chain category of perfluorinated carboxylate chemical substances with perfluorinated carbon chain lengths equal to or greater than nine carbons and less than or equal to fourteen carbons.

This requirement applies to all articles (components) in the products at 25 ppb for the sum of LC-PFACs and their salts (or detection limit for smaller sample), and 260 ppb for the sum of LC-PFAC-related substances.

C8 (PFOA) is an LC-PFAC, but the regulation of PFOA has been moved to the EU POP regulation. The REACH Restriction is limited to C9-C14. The derogations should match in both regulations, as the LC-PFAC occur together, however there are currently discrepancies between derogations under POP and REACH.

C.2.2.2 PERFLUOROXYALKANE (PFA) DEROGATION

Under derogation (exemption) 10 of Entry 68 to the REACH Restrictions, PFA polymers are permitted up to 2 ppm sum of C9-C14 (PFNA and longer) until 25 August 2024. This limit is reduced to 100 ppb as of 26 August 2024.

The POP restriction for PFOA (C8) does not contain this derogation, however - since the REACH Restriction derogation would be ineffective without C8 being included, many companies have assumed that the derogation should extend to PFOA. The clarification has been submitted by industry as a derogation request / clarification as part of the REACH PFAS restriction consultation.

C.2.2.3 REACH FORMALDEHYDE RESTRICTION

The EU REACH restriction for formaldehyde emission in consumer and indoor products is tested according to ISO 16000-9:2006/Cor 1:2007 + ISO 16000-3:2022 using an emission test chamber and high-performance liquid chromatography with diode-array detection (HPLC-DAD).

The circuit board is the higher risk electronic component for formaldehyde emissions in an electronic product and is commonly the major assembly tested for formaldehyde emissions.

C.3 Note Regarding Proposition 65

Compliance for California Proposition 65 is a risk-based assessment consisting of screening testing, engineering review, and in-depth testing of high-risk materials. The evaluation is structured to include all major applicable California Proposition 65 substances, with a focus on substances included in known California Proposition 65 prosecutions and applicable exposure scenarios.

According to the California Code of Regulations New Section 12900 (a) 4, the product can be identified as having no intentional exposure if “all the reported results show that the chemical in question was not detected.” In the event of a detected presence of a substance, the appropriate test or recommendation will be applied based on settlement agreements and agreed upon exposure risks. Trace monomers that are inhalation risks only or have very high safe harbor limits will be deemed low risk for the purpose of this report. The burden of investigation for these trace monomers is disproportional to their risk of non-compliance for these substances. Exceptions to this case may be made at the specific request of the client, or specific identification of the route of exposure being food contact or wearable devices. The manufacturer (or other actor providing an exposure) is ultimately responsible for determining if a warning is required for substances identified in this report.

The risk assessment is based on reasonably foreseeable exposure scenarios, exposure risks for specific substances, and previous California Proposition 65 notices. Complicated or creative exposure scenarios (such as transferal of substances to hands through routine touching of parts containing readily available surface amounts of a listed chemical and the listed chemical subsequently ingested via hand-to-mouth behavior, hand-to-food-to-mouth behavior, or through hand-to-cigarette-to-lung behavior) are not necessarily covered in the risk assessment.

If the determination of a specific exposure level is required, additional work using the Office of Environmental Health Hazard Assessment (OEHHA) Safe Use Determination (SUD) models could be conducted in some cases.

The substances evaluated under Proposition 65 are according to the list available as of the effective date noted in the preamble of the report.

For products that are sterilized with ethylene oxide, only one material will be identified as being a risk, but it is to be understood that the risk applies to the product as a whole.

Phthalates Limits: The limits below are based on exposure measurements obtained through surface wipe testing using sebum (artificial sweat) and comparing them against the appropriate Proposition 65 safe-harbor limits, which Claigan uses to determine compliance. The limits below are based on empirical data for standard situations.

Phthalate	Limit (ppm)
DEHP	10,000
BBP	10,000
DBP	1,000
DIDP	10,000
DINP	5,000

C.4 Note Regarding EU Batteries Regulation

Batteries have been reviewed for compliance with the material restriction requirements of the EU Batteries Regulation. Restrictions are assumed to be at the battery cell level and do not extend to RoHS compliance electronic components used in the battery pack.

C.5 Note Regarding EU Packaging Directive and US Toxics in Packaging

Packaging compliance has been assessed to the materials restrictions for EU Packaging Directive and/or the US Toxics in Packaging Legislation.

Noncompliance risks for packaging regulations will be identified in the XRF elements table for Pb, Cd and Hg, and the Hexavalent Chromium (Cr^{6+}) Screening table, or in related analytical testing tables. Failures for packaging will be denoted Fail(pkg); Inconclusive measurements for packaging will be denoted Inc(pkg).

Substances	Limit (ppm)
Sum of Pb, Cd, Hg, Cr^{6+}	100

C.6 Notes Regarding EU Medical Device Regulation (MDR)

The risk-based approach involves screening of materials using the appropriate equipment, a technical assessment, and follow up testing by appropriate methods to further quantify identified risk substances, if necessary. Depending on the material of interest, the specific testing method may vary.

The list of high-risk category 1 carcinogens, mutagens and reproductive toxins (CMR's) and endocrine disruptors (ED's) is based on a detailed review of the EU categorized Category 1 CMR's and whether the material is reasonably likely to be in a medical device over 0.1% w/w. For example, many of the Category 1 CMR's are monomers of polymers and are unlikely to be in most plastics in excess of 0.1 % w/w concentration.

The exact application of the product will not necessarily be clear to Claigan, and Claigan relies on guidance from the customer regarding application and invasiveness of the device or material/samples in terms of the categories below.

C.6.1 Annex I, Chapter II, 10.4.1. Design and Manufacture of Devices (CMR's and ED's)

Assessment of compliance for EU Medical Device Regulation restricted substances follows the risk-based approach as it applies to category 1 CMR's and endocrine disruptors. This assessment is referred to in this test report as *MDR 10.4.1*. Substances identified under MDR 10.4.1 may also require labelling under Section 23.4 (s).

Review of materials for 10.4.1 of the EU MDR depends on the client's identification of materials that are invasive and human contacting, used to (re)administer liquids or gases to/from the body, or transport or store such liquids or gases to be (re)administered to the body.

Thin coatings and the substrates to which they are applied will be considered a single material in cases where the coating cannot be effectively separated from the substrate, and the coating would not provide a mechanical barrier to the substrate material. This discourages the omission of substrate substances from 10.4 labelling and justification, and encourages the application of thinner coatings to limit the residual presence of potential substances of concern in applied coatings

Unless indicated that ethylene oxide (EtO) is excluded from the risk assessment, the largest high-risk part from an EtO-sterilized product, based on EtO material absorbance, will be assessed for residual EtO concentration to represent the worst-case residual concentration in the product.

C.6.2 Annex I, Chapter II, 10.6. Design and Manufacture of Devices (Nanomaterials)

XRF screening of plastics includes elements that could represent substances in nanomaterial form (specifically calcium, silicon, titanium, iron, zinc, chromium, barium and aluminum.) If aggregation or agglomeration could represent over 50% of the plastic material composition, the material is reviewed for specific additives and the risk of these being present in nanomaterial form.

Biocides identified by the client as being present, are reviewed for whether or not they meet the criteria of nanomaterials.

C.6.3 Annex I, Chapter III, 23. Label and instructions for use, Section 23.4 (s)

Assessment of compliance for EU Medical Device Regulation labelling requirements for allergens follows a risk-based approach. This assessment is referred to in this test report as *MDR 23.4.*

The review currently includes nickel and latex, however additional allergens will be added into future reviews as they become accepted as allergens in medical devices.

C.7 Note Regarding Health Canada Medical Device Licensing (DEHP, BPA)

Health Canada requests that Class II and above medical device licencing applications disclose the presence of DEHP in excess of 0.1% by weight of the device, and the presence of BPA or BPA-derived materials.

C.8 Note Regarding US FDA (Latex Labelling)

The US FDA requires that labelling be provided for medical devices and related packaging that contain latex natural rubber.

C.9 Note Regarding Australia Asbestos Ban and Prohibition of Products Containing Asbestos in Canada

Components and materials are reviewed for risk of containing asbestos materials. A priority is placed on material containing fibres or talc. Because of errors and gaps in knowledge in the supply chain, the potential for asbestos to be bound in a plastic or wax matrix, potential unknown uses of asbestos, and the potential for trace levels of asbestos contamination in materials, there is opportunity for a risk of asbestos to be omitted from the review or documentation of risks.

C.10 Note Regarding EU Persistent Organic Pollutants (POP)

Components and materials are reviewed for risk of containing SCCP's, PBDE's (the sum of tetra, penta, hexa, hepta, deca), PFOA, PFOS and derivatives, and HBCDD in regulated concentrations.

When all Group 1 phthalates are detected below a concentration of 10,000 ppm in PVC, concentrations of SCCP's are not expected to exceed 1000 ppm. In these cases, the SCCP risk is considered to be resolved. However, since SCCP's are restricted, testing will be prioritized whenever possible.

Substances	Limit (ppm)
SCCP	1,500
PBDE's (non-RoHS)	500
PFOA (non-medical)	0.025
PFOA (medical - invasive - 2025)	0.025
PFOA (medical - non-invasive)	2
PFOS	1,000
HBCDD	75

If a sample is risked for PFOA, it should be understood that the risk applies to PFOA and its related compounds. The risk for PFOA is considered to be low if the result from XRF-WD is inconclusive. There are additional application specific limits not listed above that may supersede those in the table. These applications will be considered when determining compliance.

C.11 Note Regarding Australia Persistent Organic Pollutants (Australia POP)

Components and materials are reviewed for risks for applicable restrictions under the Industrial Chemicals Environmental Management (Register) Instrument 2022 (IChEMS). IChEMS, known colloquially as Australia POP, is the Australian implementation of the UN Stockholm Convention and is intended to be similar to the EU POP Regulation.

Risk assessments for substances overlapping with EU POP are handled in the same way as described under that legislative section.

Substances	Limit (ppm)
SCCP	1,500
DecaBDE	1000
Dechlorane Plus	100
UV-328	100
PFOA	0.025
PFOS	0.025
PFHxS	0.025
HBCDD	100

Note – the regulated levels identified in the table may have different thresholds or interpretations over time, and for specific applications. For substances without specific limits, published data from the EU Waste Industry on levels of unintentional contaminants was used.

C.12 Note Regarding Canadian Prohibition of Certain Toxic Substances Act SOR/2012-285

Components and materials are reviewed for risk of containing SCCP's in regulated concentrations.

When all Group 1 phthalates are detected below a concentration of 10,000 ppm in PVC, concentrations of SCCP's are not expected to exceed 1000 ppm. In these cases, the SCCP's risk is considered to be resolved. However, since SCCP's are restricted, testing will be prioritized whenever possible.

Substances	Limit (ppm)
SCCP's	1,500

C.13 Note Regarding Halogen Free

Components and materials are reviewed for risk of containing Cl and Br according to EN/IEC 61249-2-21 Halogen Free Standard.

Substances	Limit (ppm)
Cl	900
Br	900
Cl+Br	1,500

C.14 Note Regarding Regulation of Certain Chemical Substances and Mixtures under Section 6 of the Toxic Substances Control Act, 40 CFR Part 751

Components and materials are reviewed for risk of containing decaBDE, PCTP, and PIP (3:1) in regulated concentrations.

Due to the rare, but open-ended potential uses for PIP (3:1), Claigan will restrict the engineering review to materials where it is most commonly found including BPA epoxies, PVC, and polyurethane foam.

Substances	Limit (ppm)
decaBDE	1,000
PCTP	10,000
PIP (3:1)	1,000

C.15 Note Regarding Significant New Uses of Chemical Substances, 40 CFR Part 721

With respect to: Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule

The term LC-PFAC refers to the long-chain category of perfluorinated carboxylate chemical substances with perfluorinated carbon chain lengths equal to or greater than seven carbons and less than or equal to 20 carbons. Due to the rarity of LC-PFAC chemical substances over 14, testing is limited to lengths of 14 carbons.

This requirement applies to any external or accessible coating in which LC-PFAC substances are present above the limit of detection (25 ppb for large samples.)

Due to the potential complexity of certain products, manufacturers should take actions "that are commensurate with the company's perceived likelihood that a chemical substance might be a part of an article". Based on this concept, a maximum of 5 representative groups of high-risk parts would be tested for LC-PFAC.

Restrictions applicable to perfluoroalkyl sulfonate chemical substances only apply to carpet.

C.16 UK RoHS, UK REACH, UK POP

All EU derived UK regulations are tested with the same methodologies as their EU counterparts. The only differences are the substances applicable under each regulation (as noted in the results table at the beginning of the report).

C.17 Swiss ORRChem

Swiss ORRChem is intended to mirror the same substance restrictions as EU REACH Restrictions. See **C.2.2**.

C.18 Reportable PFAS (Intentionally Added)

Identification of intentionally added perfluoroalkyl and polyfluoroalkyl substances (PFAS) according to the requirements of various US state-level legislations and similar emerging PFAS reporting regulations.

The process identifies the presence of fluorinated substances by FTIR, XRF-WD, and CIC. Additional investigation can be conducted on the XRF and FTIR results to estimate the type of PFAS. The presence of unintentionally added monomer PFAS is handled separately by the EU REACH Restriction and POP processes.

The reporting PFAS (Intentionally Added) process includes US EPA Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances (40 CFR 705) and state level PFAS reporting legislations based on the Northeast Waste Management Officials' Association, Inc. (NEWMOA) model legislation (*e.g.* Maine and Minnesota).

C.19 PFAS (P26)

P26 testing is used to identify PFAS salts as listed in Appendix B. There are technically hundreds of thousands of PFAS salts. However, all of these salts degrade into the fundamental carboxylates represented by the 26 substances tested here. Any regulated PFAS salt (in articles) present would produce one or more of the fundamental carboxylates in the P26 test suite.

Testing is by LC-MS/MS to an industry standard list (P26) of perfluoroalkyl carboxylates and substances that can degrade into perfluoroalkyl carboxylates. The list includes 26 short-chain and long-chain, linear- and branched-perfluoroalkyl carboxylates, perfluorotelomer alcohols, and perfluorotelomer acrylates. These substances are the most common substances in their families. Other rarer variants may exist.

Substances are reported as detected. Specific regulation of a substance (if any) will depend on the jurisdiction and product.

C.20 PFAS (Extended P13)

P13 testing is for the fundamental PFAS sulfonate salts as listed in Appendix B. PFAS sulfonate salts degrade into one or more of these fundamental sulfonate salts or PFAS carboxylate salts (P26).

Substances are reported as detected. Specific regulation of a substance (if any) will depend on the jurisdiction and product.

C.21 France MOSH/MOAH

The restriction applies to the following:

Substance	Range	Inconclusive Limit	Non Compliant Limit
MOAH	C10 to < C16	≥ 2 ppm	Total PAH ≥ 1 ppm
MOAH	C16 to ≤ C25	≥ 2 ppm	Total PAH ≥ 1 ppm
MOSH/POSH	C16 to ≤ C35	N/A	≥ 1000 ppm

In the case of a positive linear MOAH result (C10 to < C16 or C16 to ≤ C25), a PAH test is used to determine if most commonly occurring applicable cyclic substances are present.

C.22 General Disclaimer

Because of errors and gaps in knowledge in the supply chain, and potential unknown uses of some regulated substances or unknown applications of the client-provided samples, there is opportunity for a substance or application to be omitted from the review.

Materials that are present in very small or dispersed quantities (e.g. films, adhesives, etc.) may also be at risk of being omitted from the review.

Modification of the test report is not permitted by the client. Any unauthorized modifications render the conclusions null and void. If a third-party presents a modified report to Claigan, Claigan is entitled to note to the third-party that modifications have been made.

References

[1] Thermo Scientific, *RoHS Compliance Screening – Elemental Limits of Detection in Metals and Polymers*, Doc. AN44808 (2008).
[2] A.B. Fialkov et al., 10th Annual Meeting of AICS, *isranalytica.org.il/Abstracts/Fialkov.DOC* (2007).