Restricted Materials Conformity Report

CETR-IRD15.1

Prepared for:	**Iridium**
Part Name:	**9603N**
Part/Model Number:	**-**
Samples Received Date:	November 13, 2018
Testing Period:	November 26, 2018
Tests Requested:	RoHS Directive 2011/65/EU and its amendment directives, in particular, Commission Delegated Directive 2015/863 to restrict four phthalates REACH Regulation 1907/2006 and its amendment regulations, including PFOA/PFOS POP Regulation 850/2004 and its amendment regulations
Date of Report:	November 28, 2018

Results

Directive / Regulation	Conclusions	Substances
RoHS 2011/65/EU	Compliant	-
RoHS 2015/863	Compliant	-
REACH 1907/2006 (33)	Compliant	-
REACH 1907/2006 (67)	Compliant	-
POP 850/2004	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.] Further testing/evaluation of identified substances by Claigan is required to address remaining risks.
Open risk:	Identified substance risks require client information or feedback to resolve.
Not compliant:	Not compliant for identified substances.

Test Summary

Reference:	EN 62321-2: 2013 [Modified]: Disassembly, Disjunction, and Mechanical Sample Preparation EN/IEC 62321-3-1:2014 [Modified]: Screening. Lead, Mercury, Cadmium, Total Chromium, and Total Bromine by X-Ray Fluorescence Spectrometry
Screening Procedures:	X-Ray Fluorescence Spectroscopy (XRF) ChromateCheck® Test Strips Fourier Transform Infrared Spectroscopy (FTIR) Engineering Analysis
Follow-up Procedures:	None required

Revision History

Rev	Description	Written By	Reviewed By	Date
1	Initial release	Iain Calder	Chris Scully	November 28, 2018

1 Test Results

For additional information on testing and regulatory thresholds, and exemption notation, please see Appendices A and B of this report.

1.1 XRF Spectroscopy

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 analyzer (Section **A.2**).

1.1.2 Elements Listed Under RoHS

Sample		Results (ppm)				Conclusion
Number	Description	Pb	Cd	Hg	Br	
60645-1	Sticker A	<LOD	<LOD	<LOD	<LOD	Pass
60645-2	Sticker B	<LOD	<LOD	<LOD	<LOD	Pass
60645-3	Metal Cover A	<LOD	<LOD	<LOD	<LOD	Pass
60645-4	Metal Cover B	<LOD	<LOD	<LOD	<LOD	Pass
60648-1	Metal Frame	<LOD	<LOD	<LOD	<LOD	Pass
60648-2	PCB Board	139 ± 82	<LOD	<LOD	31816 ± 1773	Pass(Br)
60648-3	Solder	<LOD	<LOD	<LOD	1740 ± 310	Pass(Br)
60648-4	Black Connector	<LOD	<LOD	<LOD	<LOD	Pass
60648-5	Metal Circular Connector	<LOD	<LOD	<LOD	<LOD	Pass
60648-6	Iridium Chip	<LOD	<LOD	<LOD	256 ± 24	Pass
60649-1	Sticker	<LOD	<LOD	<LOD	<LOD	Pass
60649-2	Metal Frame	<LOD	<LOD	<LOD	<LOD	Pass
60649-3	Small White Component	<LOD	<LOD	<LOD	<LOD	Pass

1.1.3 Additional Elements

Sample		Results (ppm)		
Number	Description	Ni	Sb	Cl
60645-1	Sticker A	210 ± 128	91 ± 38	10143 ± 932
60645-2	Sticker B	206 ± 107	59 ± 33	<LOD
60645-3	Metal Cover A	175670 ± 940	<LOD	N/A
60645-4	Metal Cover B	165160 ± 870	<LOD	N/A
60648-1	Metal Frame	159980 ± 890	<LOD	N/A
60648-2	PCB Board	9184 ± 502	<LOD	<LOD
60648-3	Solder	33140 ± 1850	<LOD	N/A
60648-4	Black Connector	4421 ± 123	<LOD	<LOD
60648-5	Metal Circular Connector	10020 ± 980	<LOD	N/A
60648-6	Iridium Chip	148 ± 46	<LOD	<LOD
60649-1	Sticker	<LOD	<LOD	<LOD
60649-2	Metal Frame	152950 ± 1090	<LOD	N/A
60649-3	Small White Component	6571 ± 560	<LOD	<LOD

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

1.2 ChromateCheck®

Sample Number	Sample Description	Conclusion
60645-1	Sticker A	Pass
60645-2	Sticker B	Pass
60645-3	Metal Cover A	Pass
60645-4	Metal Cover B	Pass
60648-1	Metal Frame	Pass
60648-2	PCB Board	Pass
60648-3	Solder	Pass
60648-4	Black Connector	Pass
60648-5	Metal Circular Connector	Pass
60648-6	Iridium Chip	Pass
60649-1	Sticker	Pass
60649-2	Metal Frame	Pass
60649-3	Small White Component	Pass

1.3 FTIR Spectroscopy

1.3.1 Testing

FTIR spectra were obtained from all samples identified as PVC with a risk of phthalates and/or samples at risk of containing fluorocarbons. The presence of these compounds is considered likely:

1. If a spectrum exhibits peaks in both of the ranges from 1597-1603 cm^{-1} and 1577-1583 cm^{-1}, it is likely that the sample contains phthalates and should undergo further testing by GC/LC-MS.
2. If a spectrum identifies the material as potentially being a fluorocarbon amongst its top ten potential materials matches, it is likely that the sample contains fluorocarbons and it should undergo further testing by GC/LC-MS.

1.3.2 Results

FTIR spectroscopy testing has been carried out on the sample shown in the table below.

Sample		Results (present or not present)
Number	Description	Fluorocarbons
60649-1	Sticker – Brown Side	Not present
60649-1	Sticker – White Side	Not present

1.4 Engineering Analysis

Sample		REACH		POP and RoHS3	
Number	Description	Risk	Comments	Risk	Comments
60645-1	Sticker A	Low		Low	
60645-2	Sticker B	Low		Low	
60645-3	Metal Cover A	Low		Low	
60645-4	Metal Cover B	Low		Low	
60648-1	Metal Frame	Low		Low	
60648-2	PCB Board	Low		Low	
60648-3	Solder	Low		Low	
60648-4	Black Connector	Low		Low	
60648-5	Metal Circular Connector	Low		Low	
60648-6	Iridium Chip	Low		Low	
60649-1	Sticker	Low		Low	
60649-2	Metal Frame	Low		Low	
60649-3	Small White Component	Low		Low	

NOTE: Unless otherwise indicated, Low Risk was determined by Engineering Analysis.

2 Photographs of the Parts

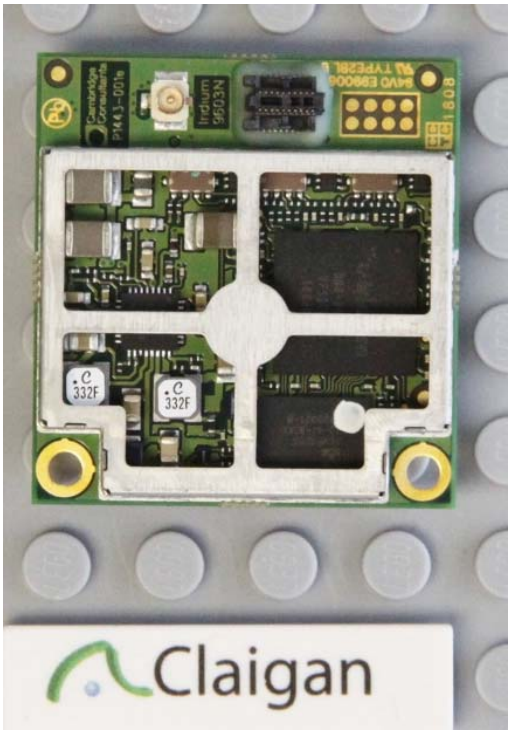
2.1 Parts as Received

60643

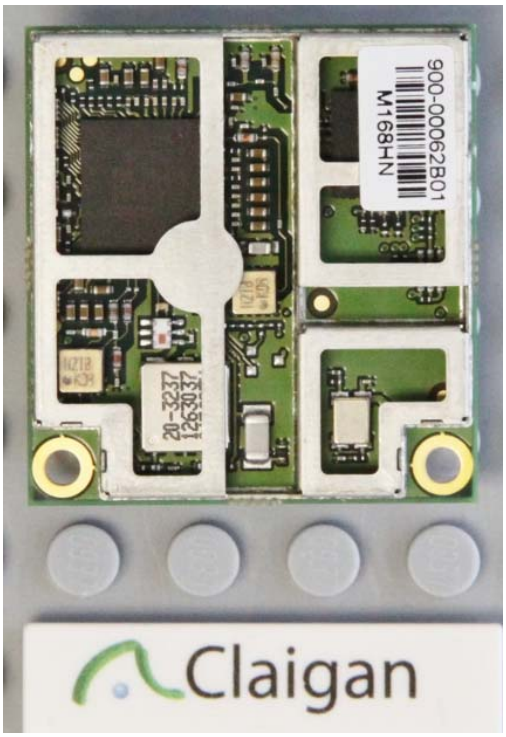
60644

2.2 Constituent Samples

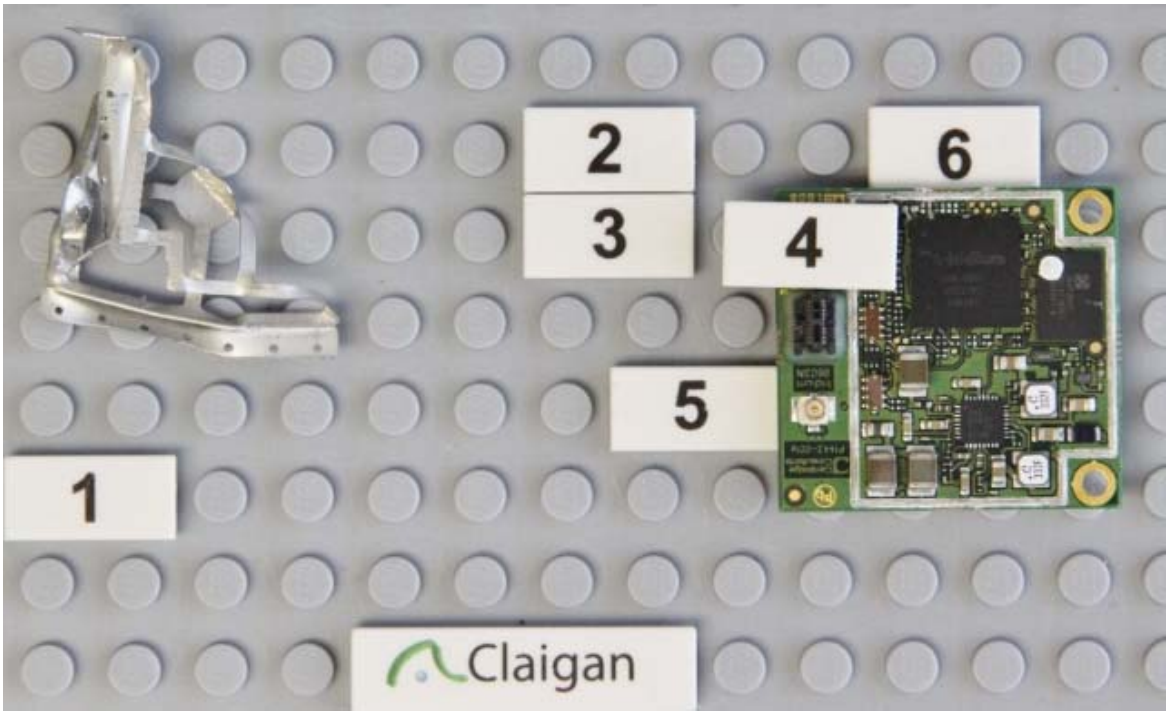
60645



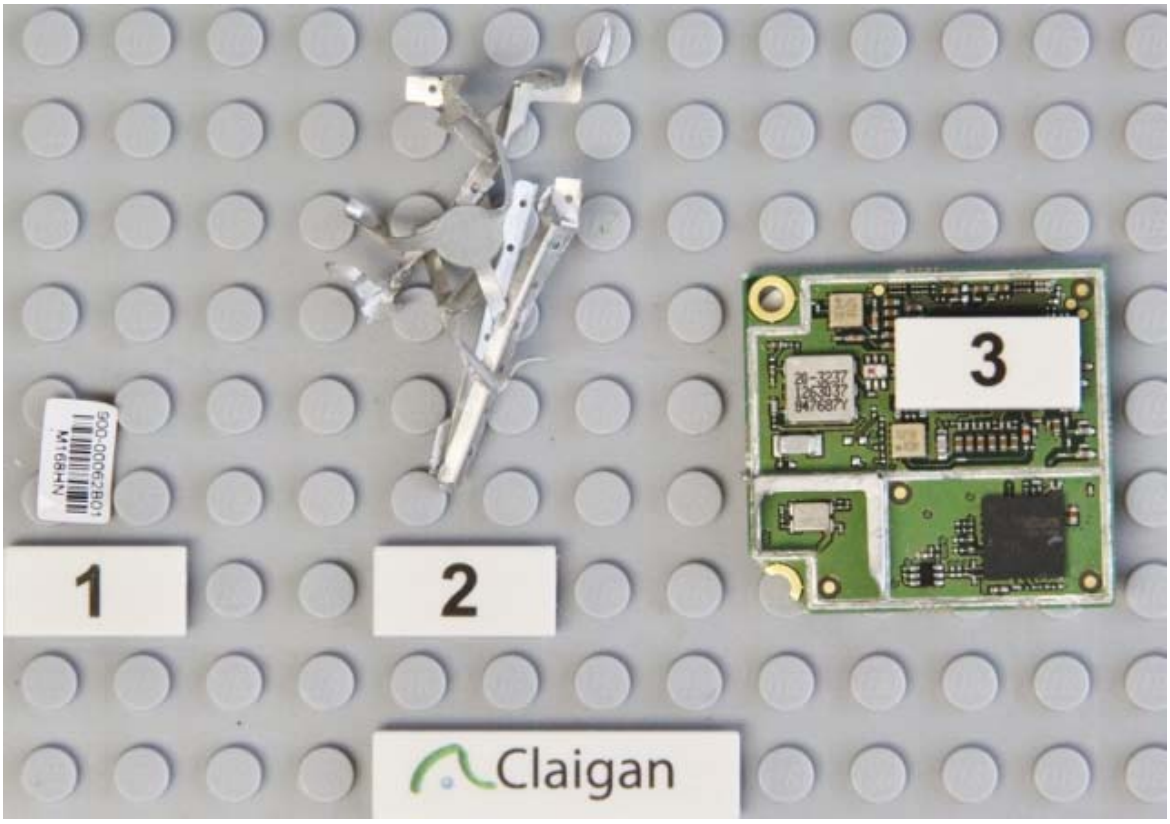
60646 Exploded view



60647 Exploded view



60648

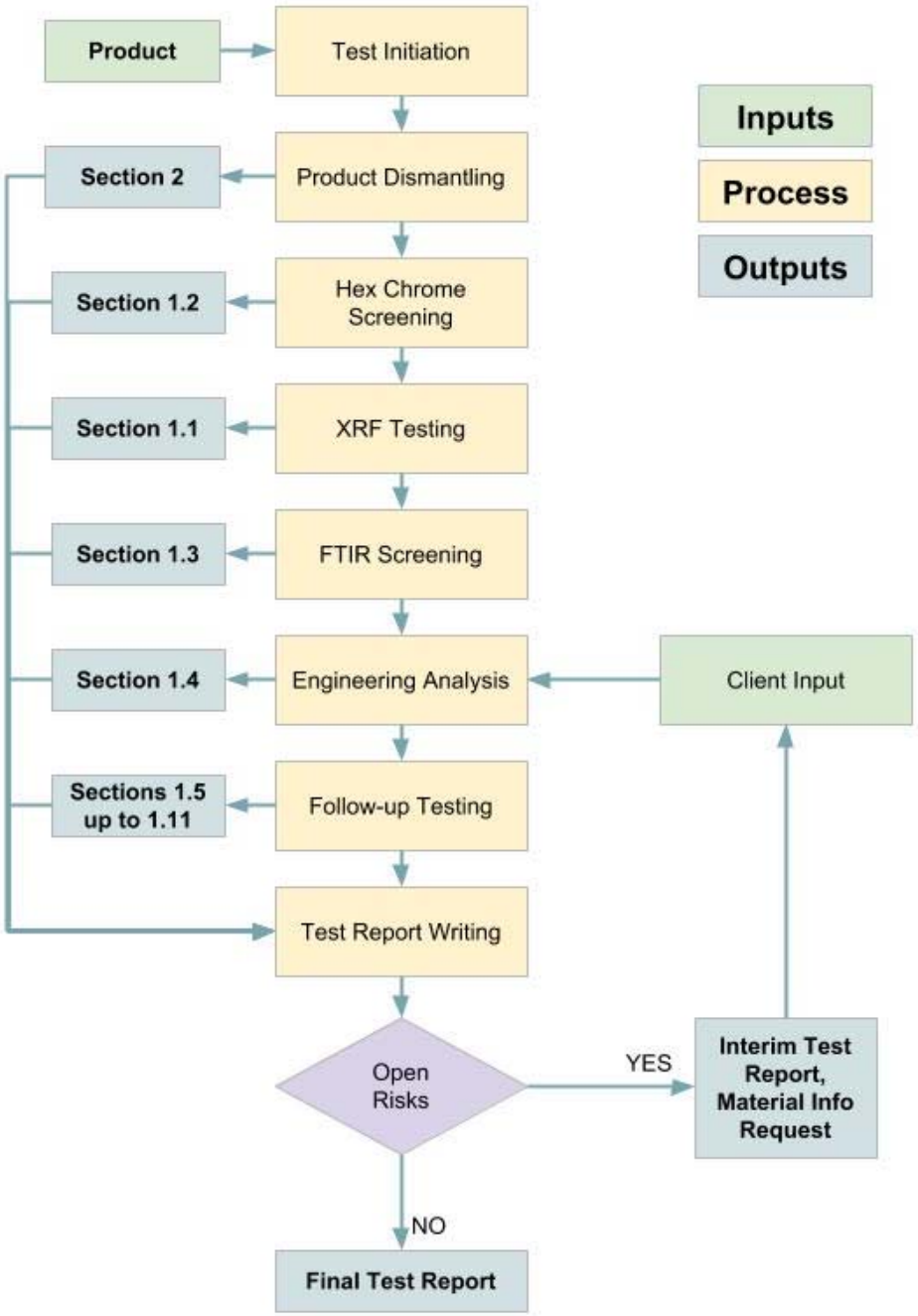


60649

Appendices

Appendix A Test Methodology

A.1 Product Analysis Process Flow Chart



A.2 X-Ray Fluorescence Spectroscopy (XRF)

XRF spectroscopy was carried out with a Niton® XL3t XRF Analyzer made by Thermo Fisher Scientific or with an XOS® HD Mobile101 XRF analyzer made by XOS.

Each device directs x-rays at the target sample, 50kV for the Niton and 25-50kV for the XOS. Their 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:

Element	Niton[1]						XOS[2]		
	Polymers		Metals				Polymers		Metals
	PE	PVC	Al	Fe	Cu	Sn	PE	PVC	
Pb	5	15	12	60	75	120	0.8	1	5-30
Cd	13	15	10	25	35	220	2	7	2-55
Hg	6	30	23	105	150	165	1	2	1-50
Br	3	8	5	20	25	35	1	1	N/A
Ni	12	75	95	350	175	600	-	-	-
Sb	22	25	15	50	60	300	6	7	5-35
Cl	10000	N/A	N/A	N/A	N/A	N/A	100	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.

A.3 ChromateCheck® Swab Test Strips

A ChromateCheck® Swab contains two glass ampoules with the reagents required for the colorimetric detection of chromium (VI), i.e. Cr6+ or hexavalent chromium. One ampoule contains a dye reactive with Cr6+ which under the proper conditions of pH and solvent turns deep pink/purple. The second ampoule contains buffers and solvents required to optimize the reaction of Cr6+ with the dye. The reaction leads to a light pink to deep purple result on the tip of the swab (depending on the concentration of Cr6+), indicated as a Fail. Where no colour change of the swab occurs, or for materials known to not contain Cr6+ (such as plastics), a Pass is indicated.

Colour saturation increases monotonically with concentration, but in practice the test provides a quick and reliable check for the presence or absence of chromium (VI) with a sensitivity of 0.02µg and a maximum reading of approximately 5µg when the colour becomes fully saturated[3]. The technique is essentially qualitative since it is difficult to determine what quantity of sample is being tested when a swab is used.

ChromateCheck® strips use a direct measurement technique – no preparation is required except for scratching the surface of the sample.

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-1506, “Common Locations of Restricted Materials”.

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-1506 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 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[4]. This translates into ppb even for very small samples although routine measurements are usually limited to ppm.

For Proposition 65, risk is only definitively determined if the release or leaching rate is measured. In the case of organic compounds, the sample is soaked in an artificial sweat solution for 24 hours at 37 °C and then the concentration of the substance in the solution is measured by LC-MS.

A.6 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[5]. All elements can be quantified by ICP-OES except C, H, O, N (components of the solvent), and the halogens.

EU standard EN 62321:2009 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.

A.7 EN 1811 and EN 12472

For EU nickel testing standards (EN 1811, EN 12472) 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. 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 $\mu g/cm^2$/week. The compliance limit for EN 1811 is defined as:

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

A.8 Surface Wipe Test

A variation on this procedure is described in NIOSH 9100, 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) 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^{6+}	Standard occasional contact	<16
Others	Standard occasional contact	ND

A.9 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 = $wavelength^{-1}$).

A.10 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 62321-7-1 (protective coatings) or EN 62321-7-2 (polymers and electronics).

For EN 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 Cr6+ from its characteristic absorption spectrum. The lower limit on sensitivity by this method is 0.1 µg/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 ChromateCheck® solvent) can be used first to remove the polymer. This procedure is suggested by EN 62321-7-1 in the case of coated surfaces, but it is not part of the official test.

For EN 62321-7-2 the sample is placed in an organic solvent to prepare the material, followed by an alkaline digestion procedure to extract the Cr6+. Then the analysis proceeds as for EN 62321-7-1.

Note that a qualitative (visual) determination of the presence of Cr6+ can also be performed by adding a Cr6+ sensitive dye to the solution. The dye is 1,5-diphenylcarbazide, the same dye used with the ChromateCheck® swab test.

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.11 Asbestos Testing

Asbestos testing is generally carried out without sample preparation. 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 Notes on Regulations

B.1 Notes Regarding RoHS

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

Assessment of compliance for RoHS restricted substances (Pb, Hg, Cd, Cr^{VI+}, 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 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/FAIL/Inconclusive 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*
Br	1000 ppm (as PBB's or PBDE's)	<1500 ppm	≥1500 ppm	N/A

* 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. **Inconclusive** results for Br are resolved using a material-type risk-based assessment that includes analytical review by GC-MS for PBB/PBDE content for samples of sufficient size.

Legend for Pass by Exemption or other noted conditions:

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

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

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.

13a: RoHS Exemption III 13(a): Pb in optical glass.

13b: RoHS Exemption III 13(b): Cd and Pb in filter glasses, and glass for reflectance purposes.

21: RoHS Exemption III 21: Pb and Cd in printing inks for the application of enamels on glasses, such as borosilicate and soda lime glasses.

IV1b: RoHS Exemption IV 1(b): Pb anodes in electrochemical oxygen sensors.

IV5: RoHS Exemption IV 5: Pb in shielding for ionizing radiation.

IV33: RoHS Exemption IV 33: Pb in solders on PCB's used in Directive 93/42/EEC class IIb mobile medical devices other than defibrillators.

Br: For Br concentrations above 1500ppm, accompanied by an Sb concentration above 1500ppm, additional work may be required to determine if the Br is in the form of PBB's or PBDE's. Metals are unlikely to contain PBB's or PBDE's and are therefore marked Pass.

Pb: Sample xxxx-x is out of scope of RoHS as it is considered part of the packaging. EU Packaging Regulation and US Toxics in Packaging restrict the RoHS heavy metals in packaging to 100ppm combined per package or package component.

B.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 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.

B.2 Notes Regarding REACH

B.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 as of the 27 June 2018, unless otherwise noted.

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.

B.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 specifed.

B.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.

B.4 Note Regarding EU Batteries Directive

Batteries have been reviewed for compliance with the restriction and/or labelling requirements of the EU Batteries Directive related to restricted materials

B.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.

B.6 Note Regarding EU Medical Device Directive (MDD)

The screening for EU Medical Device Directive materials of concern is confined to:

1. identification of materials at risk of containing natural rubber latex;
2. identification of materials at high risk of containing phthalates identified as category 1 and category 2 CMRs. Samples under consideration for phthalate risks are specifically those materials coming into contact with fluids or gasses administered to or from the body, or meant for storage of fluids or gasses.

Screening methods include a risk-based approach to identify materials at high risk of containing plasticizers and/or latex, input from the client on the exact application of the materials, and follow up testing as required.

B.7 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 (if necessary). Depending on the material of interest, the specific testing method may vary.

The list of high-risk category 1 CMR'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.

B.7.1 Annex I, Chapter II, 10.4.1. Design and Manufacture of Devices

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 or come into contact with patient-bound fluids or gasses.

B.7.2 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.

B.8 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.

B.9 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.

B.10 Note Regarding Australia Asbestos Ban

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.

B.11 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.

References

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