Restricted Materials Conformity Report

CETR-EVG01.1

Prepared for:	**Everglow**
Address:	**-**
Part Name:	**Exit Sign & Strips**
Part/Model Number:	**-**
Samples Received Date:	December 16, 2019
Testing Period:	December 23, 2019
Tests Requested:	California Proposition 65 (The Safe Drinking Water and Toxic Enforcement Act, 1986)
Date of Report:	December 28, 2019

Results

Directive / Regulation	Conclusions	Substances
Proposition 65	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 [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.
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	Jeff Hogg	December 28, 2019

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 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 except sample 12707-1, which was measured with the XOS® analyzer (Section **A.2**).

1.1.2 Table 1

Sample		Results (ppm)		
Number	Description	Pb	Cd	Hg
12707-1	Red Sign	77 ± 4	<LOD	<LOD
12707-2	Yellow Sign	<LOD	<LOD	<LOD
12707-3	Small Strip	<LOD	<LOD	<LOD
12707-4	Large Strip	<LOD	<LOD	<LOD
12707-5	Strip Backing	<LOD	<LOD	<LOD

1.1.3 Table 2

Sample		Results (ppm)			
Number	Description	Ni	Sb	Br	Cl
12707-1	Red Sign	16 ± 2	53 ± 14	<LOD	<LOD
12707-2	Yellow Sign	232 ± 22	56 ± 9	<LOD	<LOD
12707-3	Small Strip	170 ± 24	51 ± 9	<LOD	<LOD
12707-4	Large Strip	237 ± 26	46 ± 14	<LOD	<LOD
12707-5	Strip Backing	<LOD	<LOD	<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
12707-1	Red Sign	Pass
12707-2	Yellow Sign	Pass
12707-3	Small Strip	Pass
12707-4	Large Strip	Pass
12707-5	Strip Backing	Pass

1.3 FTIR Spectroscopy

1.3.1 Testing

FTIR spectra were obtained from all samples identified during XRF screening as PVC with a risk of orthophthalates (phthalates) and/or samples at risk of containing fluorocarbons.

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 (marked as present) and should undergo further testing by **GC/LC-MS**.
2. Spectra exhibiting single or no peaks are unlikely to contain orthophthalates, other than RoHS phthalates (DEHP, BBP, DBP, DIBP), at a level that would constitute a risk, and are marked “Low Risk” in this table.
3. 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 (marked as present) and it should undergo further testing by **GC/LC-MS**.

1.3.2 Results

There were no parts determined to be PVC or at risk of containing fluorocarbons during XRF screening.

1.4 Engineering Analysis

Sample		Proposition 65	
Number	Description	Risk	Comments
12707-1	Red Sign	Low	
12707-2	Yellow Sign	Low	
12707-3	Small Strip	Low	
12707-4	Large Strip	Low	
12707-5	Strip Backing	Low	

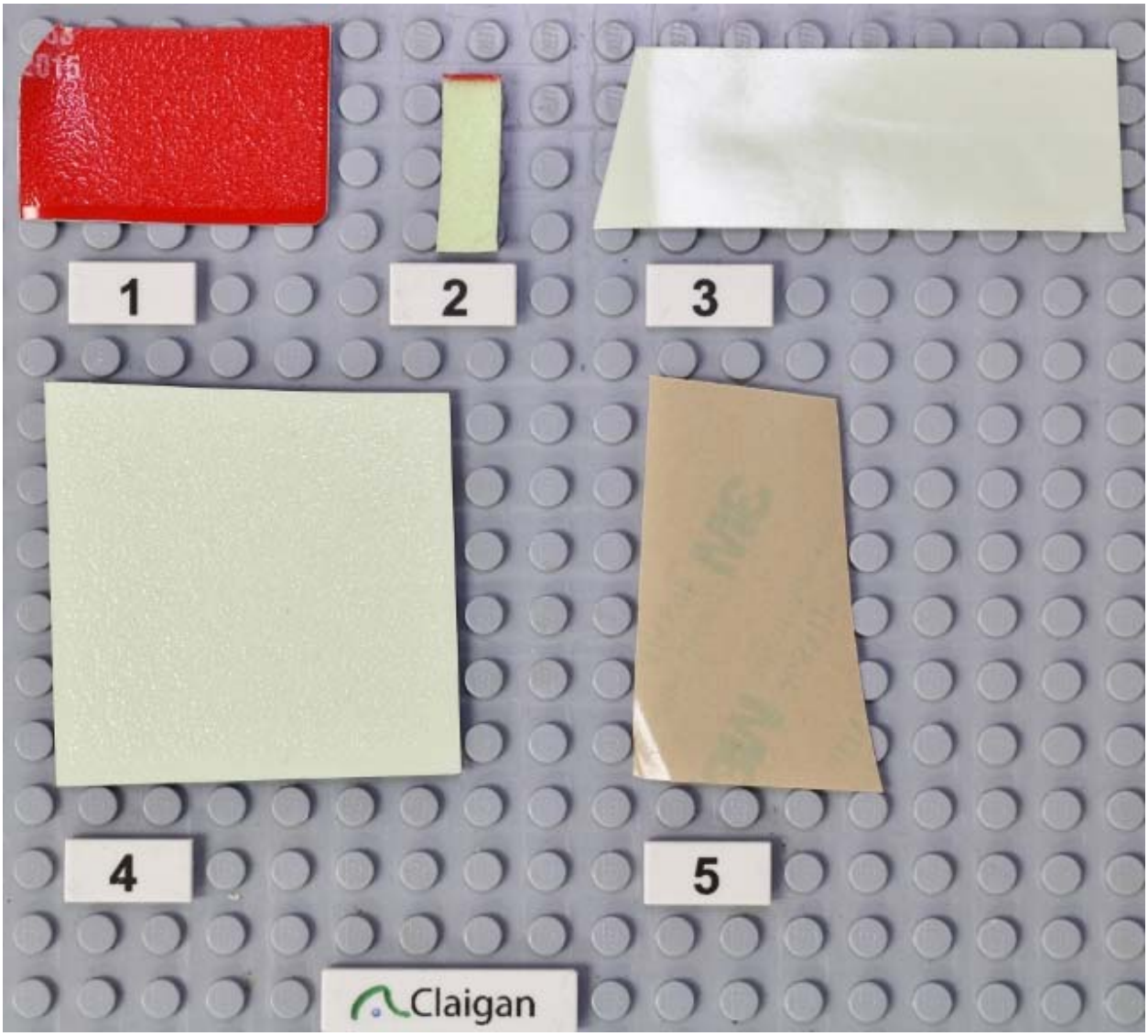
NOTE: Unless otherwise indicated, Low Risk was determined by Engineering Analysis.

2 Photographs of the Parts

2.1 Parts as Received

3420 As received

2.2 Constituent Samples

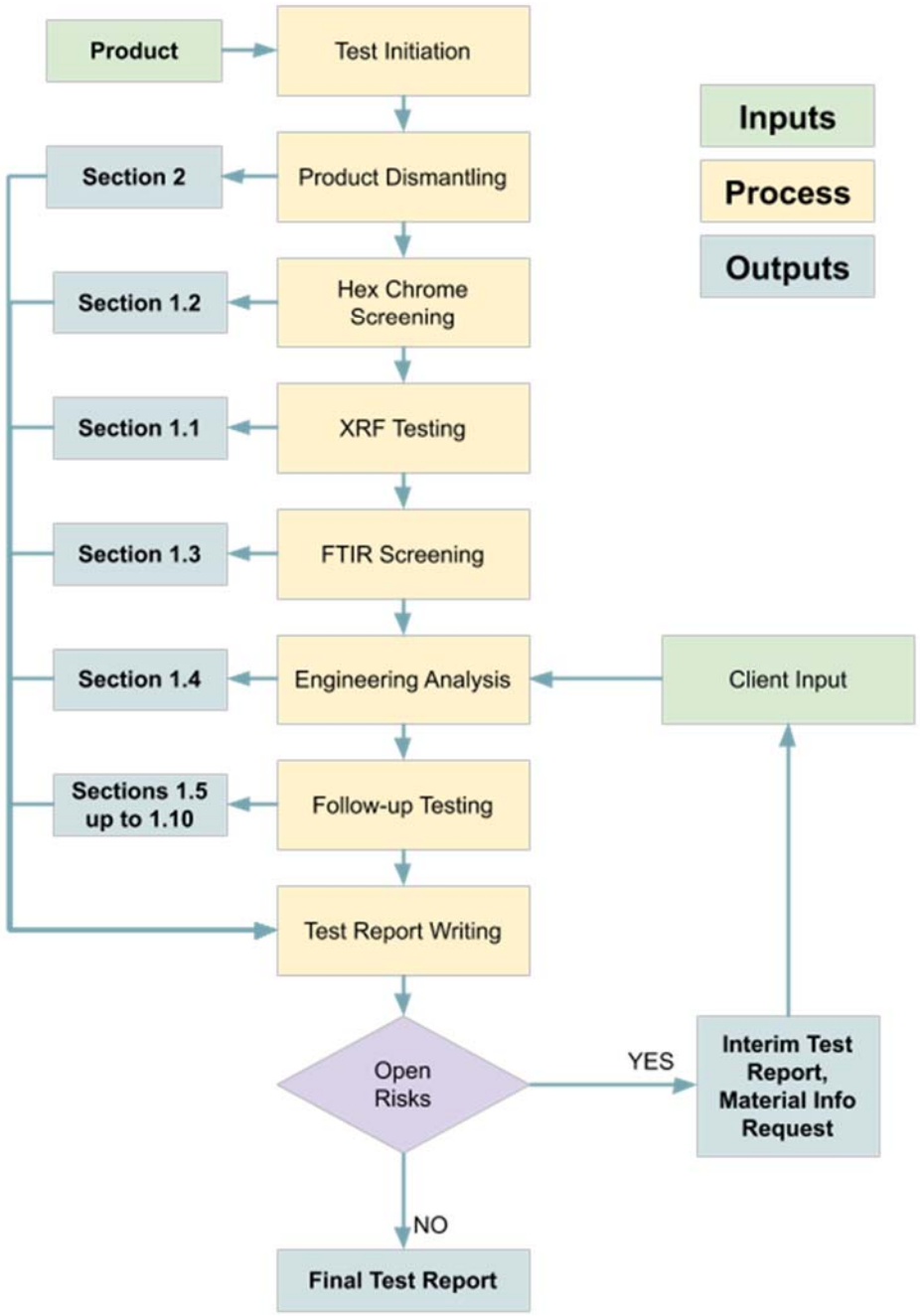


12707

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 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-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. 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.

For Proposition 65, risk is only definitively determined if the release or migration rate is measured. In the case of organic compounds, the sample is soaked in an artificial sweat or artificial sebum (skin oil) 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 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.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}).

FTIR screening for phthalates is generally effective for orthophthalates in concentrations above ~2,000 ppm with uniform distribution on the surface of the material. Orthophthalates do not have an effective use below this concentration and any orthophthalate present at that level would normally be a contamination or other unintentional presence. Due to the relationship between SCCPs, BPA, and orthophthalates, SCCPs and BPA would generally be seen as low risk if high concentrations of orthophthalates are not expected to be present.

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 62321 standards. The EN 62321 standards are not comprehensive for all situations, rely partially on risk-based judgment, and have the opportunity for error. Claigan follows the EN 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] ≤ 300 ppm*	>300 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.

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

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.

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

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 15 January 2019, 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 specified.

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.

The substances evaluated under Proposition 65 are according to the list available 1 January 2019. If PFOA/PFOS were not specifically requested by the client, these substances were not included in the evaluation.

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.

Noncompliance risks for packaging regulations will be identified in the XRF elements table for Pb, Cd and Hg, and the ChromateCheck table, or in related analytical testing tables. Failures for packaging will be denoted Fail(pkg); Inconclusive measurements for packaging will be denoted Inc(pkg).

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 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.

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 Note Regarding EU Persistent Organic Pollutants (POP)

Components and materials are reviewed for risk of containing SCCPs, PBDEs, PFOS and derivatives, and HBCDD in regulated concentrations.

B.12 Note Regarding Canadian Prohibition of Certain Toxic Substances Act SOR/2012-285, test for SCCP's

Components and materials are reviewed for risk of containing SCCPs in regulated concentrations.

B.13 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

[1] Thermo Scientific, *RoHS Compliance Screening – Elemental Limits of Detection in Metals and Polymers*, Doc. AN44808 (2008).
[2] XOS, *HD Mobile[101] 4-pager brochure rev. 102815* (2015).
[3] Hybrivet Systems, *Performance Characteristics of ChromateCheck™ Swabs II*, Application Note CR-50 (2009).
[4] A.B. Fialkov et al., 10th Annual Meeting of AICS, *isranalytica.org.il/Abstracts/Fialkov.DOC* (2007).
[5] Evans Analytical Group, *ICP-OES and ICP-MS Detection Limit Guide*, http://www.eag.com/documents/icp-oes-ms-detection-limit-guidance-BR023.pdf (2014).