



MONOKOTE® MK-6/HY
MONOKOTE MK-6 Extended Set

LEED DOCUMENTATION

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April 28, 2025

RE: MONOKOTE® Fireproofing Materials – Sustainability beyond LEED®.

GCP Applied Technologies is proud to participate in several sustainability programs that can help you design and construct a more sustainable building.

Sustainability information related to MONOKOTE® Fireproofing Materials can be found [here](#).

Contributions to LEED

MONOKOTE® Fireproofing materials are shipped in recyclable packaging and contain recycled content. We also have publicly available transparency reports to provide insight into our products. Choosing MONOKOTE® Fireproofing can help projects achieve the following LEED® V4 credits under the Building Design + Construction and Interior Design + Construction rating systems:

LEED V4	
Building Product Disclosure and Optimization – Material Ingredients	Building Product Disclosure and Optimization – Environmental Product Declarations
Low Emitting Materials	Acoustic Performance
Building Product Disclosure and Optimization – Material Ingredients	Construction and Demolition Waste

All MONOKOTE® Fireproofing materials have a Type III environmental product declaration prepared in accordance with ISO 14025, ISO 21930, ISO 14040/44, ASTM Product Category Rule (PCR) for Spray-applied Fire-Resistive Materials (SFRM) and ASTM General Program Instructions for Type III EPDs.

The Global Warming Potential of MONOKOTE® Fireproofing materials, per 1,000 kg of product may be found in the table below.

MONOKOTE®	kg CO2 eq
MK-6/HY	210
MK-6s	210
MK-6 ES	210
MK-6/GF	210
RG	210
MK-10/HB	210
MK-10/HB ES	210
MK-1000/HB	210
MK-1000/HB ES	210
Z-106/HY	493
Z-106/G	493
Z-146	621

Z-146PC	621
Z-146T	621
Z-156	621
Z-156PC	621
Z-156T	621

Regional Materials: Depending on your project location, you may also be eligible to claim a 100-mile regional sourcing multiplier for LEED® V4. MONOKOTE® Fireproofing materials are produced in the following cities in North America:

- Ajax, Ontario, Canada, Santa Ana, California
- Andover, Massachusetts (Firebond Concentrate only)

VOC – Content and Emissions ; The majority of MONOKOTE® Fireproofing products have been tested per the CDPH – CA Section 01350 Standard Method for the Testing and Evaluation of Volatile Organic Chemical Emissions from Indoor Sources using Environmental Chambers Version 1.2.

The VOC Content of our MONOKOTE® Fireproofing products are as follows:

<u>MONOKOTE® Fireproofing Product</u>	<u>Volatile Organic Compounds (VOC) reported per the Emission Standards</u>
MONOKOTE® Fireproofing	0 g/L
Firebond® Concentrate	0.60 g/L

The recycled contents of MONOKOTE® Fireproofing are shown below:

<u>MONOKOTE®</u>	<u>% Weight Post-Consumer</u>	<u>% Weight Post- Industrial</u>
MK-6/HY	7.13	0.00
MK-6s	5.13	0.00
MK-6 ES	5.13	0.00
MK-6/GF	7.05	0.00
RG	8.27	0.00
MK-10/HB	6.99	0.00
MK-10/HB ES	5.01	0.00
MK-1000/HB	5.10	0.00
MK-1000/HB ES	5.09	0.00
Z-106/HY	5.05	0.00
Z-106/G	5.13	0.00
Z-146	1.93	0.00
Z-3306	4.51	0.00
SK-III	0.00	0.00
Z-146PC	1.91	0.00
Z-146T	1.91	0.00
Z-156	1.25	0.00
Z-156PC	1.23	0.00
Z-156T	1.23	0.00
Firebond Concentrate	0.00	0.00
MK Accelerator	0.00	0.00



Contribution to the Living Building Challenge (LBC)

GCP Applied Technologies has developed Declare RED LIST FREE labels for several MONOKOTE® Fireproofing products, all of which are publicly available.

Please feel free to contact myself or any member of the MONOKOTE® Fireproofing team should you require additional information or clarification.

We look forward to MONOKOTE® Fireproofing being your product of choice when sustainability is important to you.

Sincerely,
John Dalton P.E. LEED® GA

A handwritten signature in black ink, appearing to read 'John Dalton', written in a cursive style.

Global Technical Service Manager
Fire Protection Products
GCP Applied Technologies



An Environmental Product Declaration

According to ISO 14025:2006 and ISO 21930:2017

A Corporate Average Cradle-to-gate EPD for Standard, Medium and High & Ultra High-Density Spray-applied Fire- Resistive Materials (SFRMs)

This EPD has been prepared in conformance with ISO 14025, 14040, 14044 standards and according to the requirements of ISO 21930:2017 and ASTM International's EPD program operator rules. This EPD was commissioned by the GCP Applied Technologies and is verified by ASTM International to conform to the requirements of ISO 14040, 14044, 14025 and 21930.





Environmental Product Declaration Summary

General Summary

Owner of the EPD



GCP Applied Technologies Inc. (GCPAT)

2325 Lakeview Parkway Suite 450,
Alpharetta, GA 30009 U.S.A.

Link (URL): <https://gcpat.com>

With roughly 2,000 employees and 50 manufacturing facilities worldwide, GCP Applied Technologies serves customers in more than 100 countries.

GCPAT was formed in February 2016 by the spin-off of W. R. Grace & Co.'s construction products segment and its packaging technologies business.

The owner of the declaration is liable for the underlying information and evidence.

SFRM Manufacturing Facilities

Ajax, Canada

294 Clements Rd. West
Ajax, Ontario L1S 3C6

Irondale, United States

2601 Commerce Blvd.
Irondale, Alabama 35210

Santa Ana, United States

2500 & 2502 S. Garnsey Street
Santa Ana, California 92707

Product Group and Name

Spray-applied Fire-Resistive Material (SFRM),
UN CPC 54650.

Product Description

SFRM is composed primarily of binding agents such as cement or gypsum and often contains other materials such as mineral wool, quartz, perlite, vermiculite, or bauxite along with various other ingredients

Reference Product Category Rules (PCR)

ISO 21930:2017 Sustainability in buildings and civil engineering works
- Core rules for environmental product declarations of construction products and services.

Certification Period

04.15.2022 - 04.15.2027

Declared Unit

1,000 kg of SFRM

Declaration Number

EPD 060

ASTM International
West Conshohocken, PA
www.astm.org

Date of issue: 04.15.2022
Period of validity: 5 years
Declaration #: EPD 060



EPD and Project Report Information

Program Operator	ASTM International
Declaration Holder	GCP Applied Technologies Inc.

Declaration Type

A "Cradle-to-gate" EPD (Production stage) of GCPAT's production of standard, medium and high & ultra-high-density spray-applied fire-resistive material. The declaration presents a weighted average profile for all three North American facilities operated by GCP Applied Technologies Inc. that manufacture SFRMs. Product activities covered include the raw material supply, transport, and manufacturing (modules A1 to A3). The declaration is intended for Business-to-Business (B-to-B) communication.

Applicable Countries

United States and Canada

Product Applicability

SFRMs are used as part of a building's passive fire resistance strategy. SFRMs have thermal and acoustical properties and assists in controlling condensation. However, its main use is in insulating steel, metal decking and other assemblies from the high temperatures found during a fire. SFRMs are used to delay (or prevent) the weakening of steel and the spalling of concrete in structures that are exposed to the high temperatures found during a fire. They do this by thermally insulating the structural members to keep them below the temperatures that cause failure.

Content of the Declaration

This declaration follows *Section 9; Content of an EPD*, ISO 21930:2017 Sustainability in buildings and civil engineering works - Core rules for environmental product declarations of construction products and services.

This EPD was independently verified

by ASTM in accordance with ISO 14025 and the core PCR ISO 21930:2017:

Internal

External

X

Tim Brooke, ASTM International

The Project Report

Note that the Project Report is not part of the public communication (ISO 21930, 10.1).

A Cradle-to-Gate Life Cycle Assessment of GCP Applied Technologies Standard, Medium and High & Ultra High-Density Spray-applied Fire-Resistive Materials (SFRMs). April 2022.

Prepared by



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This EPD project report was independently verified by in accordance with ISO 14025, ISO 14040/44, and the core PCR ISO 21930:2017:

Thomas P. Gloria, Ph. D.
Industrial Ecology Consultants

ASTM International
West Conshohocken, PA
www.astm.org

Date of issue: 04.15.2022
Period of validity: 5 years
Declaration #: EPD 060



1 PRODUCT IDENTIFICATION

1.1 PRODUCT DEFINITION

Spray-applied fire-resistive materials (UN CPC 54650) are composed primarily of binding agents such as cement or gypsum and often contain other materials such as quartz or bauxite along with various other ingredients. The other materials are used to help lighten the solution or to add air as an insulator. Chemical hardeners are sometimes used to either speed up hardening or to make the final fireproofing harder than the original.

Passive fire protection materials (commonly referred to as fireproofing) are used to prevent or delay the failure of steel and concrete structures exposed to fire. These materials are intended to insulate the structural members during the event of a fire, delaying any loss of the integrity of the structural members. There is an array of available fireproofing materials that can be used depending upon the specific application. Applied fireproofing is available as a wet or dry formula. It is typically sprayed but can also be troweled on. The fireproofing is generally delivered as a dry powder in bag, which is then mixed with water in the field. Modern formulas are asbestos-free and don't contain free crystalline silica. This is a company-specific EPD representing an array of available SFRMs produced at three of GCPAT's facilities located in North America and produced to various specifications as noted in Table 1. Table 1 summarizes key technical data for GCPAT SFRMs for the 2019 reference year (12 months). GCPAT SFRMs are classified in three major sub-categories based on the dry density minimum average values in pcf (pound per cubic foot). Full material selection guide and literature and the material safety data sheets are available for each of these fireproofing materials at <https://gcpat.com>.

Table 1. Technical Data for GCPAT SFRMs

Primary Binding Agent	GCPAT SFRM-Sub-category	Dry density, minimum average- in kg/m ³ (pcf)	GCPAT Brand Names
Gypsum - based	Standard density	240 (15)	MK Patch (GF Pail), MK-10/HB EXT SET WHITE, MK-10/HB EXT SET, MK-10/HB WHITE, MK-1000/HB, MK-1000/HB EXT SET, MK-10/HB, MK-10/HB EXT SET, MK-6 EXT SET, MK-6/GF, MK-6/HY, MK-6/HY EXT SET, MK-6/HY CE, MK-6/HY EXT SET, MK-6S, MK-6S CE, RG, Z-3306/G
Cement- or gypsum-based or a blend	Medium density	352 (22)	SK-3, Z-106/G, Z-106/HY, Z-3306, Z-3306 Gray, Z-3306 White
Cement- based	High & ultra-high density	640 (40)	Z-146, Z-146PC, Z-146T, Z-156, Z-156PC, Z-156T



1.2 PRODUCT STANDARD

The physical characteristics of SFRM are determined according to various ASTM standards such as, but not limited to:

- E736/E736M-19, Standard Test Method for Cohesion/Adhesion of Sprayed Fire-Resistive Materials Applied to Structural Members
- E605/E605M-19, Standard Test Methods for Thickness and Density of Sprayed Fire-Resistive Material Applied to Structural Members
- E759/E759M-92(2020)e1 Standard Test Method for Effect of Deflection on Sprayed Fire-Resistive Material Applied to Structural Members
- E760/E760M-92(2020)e1 Standard Test Method for Effect of Impact on Bonding of Sprayed Fire-Resistive Material Applied to Structural Members
- E761/E761M-92(2020)e1 Standard Test Method for Compressive Strength of Sprayed Fire-Resistive Material Applied to Structural Members
- E859/E859M-93(2020)e1 Standard Test Method for Air Erosion of Sprayed Fire-Resistive Materials (SFRMs) Applied to Structural Members
- E937/E937M-93(2020)e1 Standard Test Method for Corrosion of Steel by Sprayed Fire-Resistive Material (SFRM) Applied to Structural Members.

2 DECLARED UNIT

The declared unit is 1,000 kg, 1 metric ton) of spray-applied fire-resistive materials (SFRM).

3 MATERIAL CONTENT

Table 2 shows the weighted average generic formulations for all three sub-categories of GCPAT fireproofing materials as produced at GCPAT's three manufacturing locations. For reasons of confidentiality a portion of each SFRM is reported as "additives".

Table 2: Weighted Average Generic Formulations for Standard, Medium, High & Ultra High Density SFRMs

Standard Density		Medium Density		High & Ultra High Density	
Material composition	%	Material composition	%	Material composition	%
Stucco (CaSO ₄ ½H ₂ O)	87%	Stucco (CaSO ₄ ½H ₂ O)	54%	Bauxite	49%
Recovered paper	5%	Portland cement	31%	Portland cement	41%
Limestone	3%	Clay	6%	Clay	3%
Rest- additives	5%	Rest- additives	9%	Rest- additives	6%
Total	100%	Total	100%	Total	100%

Table 3 shows the amount of packaging materials per 1,000 kg of GCPAT SFRMs. Paper sacks are used for transporting fireproofing materials. The sacks are typically made of high-quality and weight kraft paper, usually virgin fiber.

Table 3: Packaging Materials for GCPAT SFRMs

Packaging materials	Quantity	Units (per 1,000 kg SFRM)
Paper Sacks	22.00	kg
Cardboard Core	0.30	kg

4 PRODUCTION STAGE

For this EPD, the boundary is “cradle-to-gate” or the *Production stage*, which includes the extraction of raw materials (cradle) through the manufacture of SFRM packaged ready for shipment (gate).

Downstream activity stages - Construction, Use, End-of-life, and Optional supplementary information beyond the system boundary - are excluded from the system boundary (Figure 1).

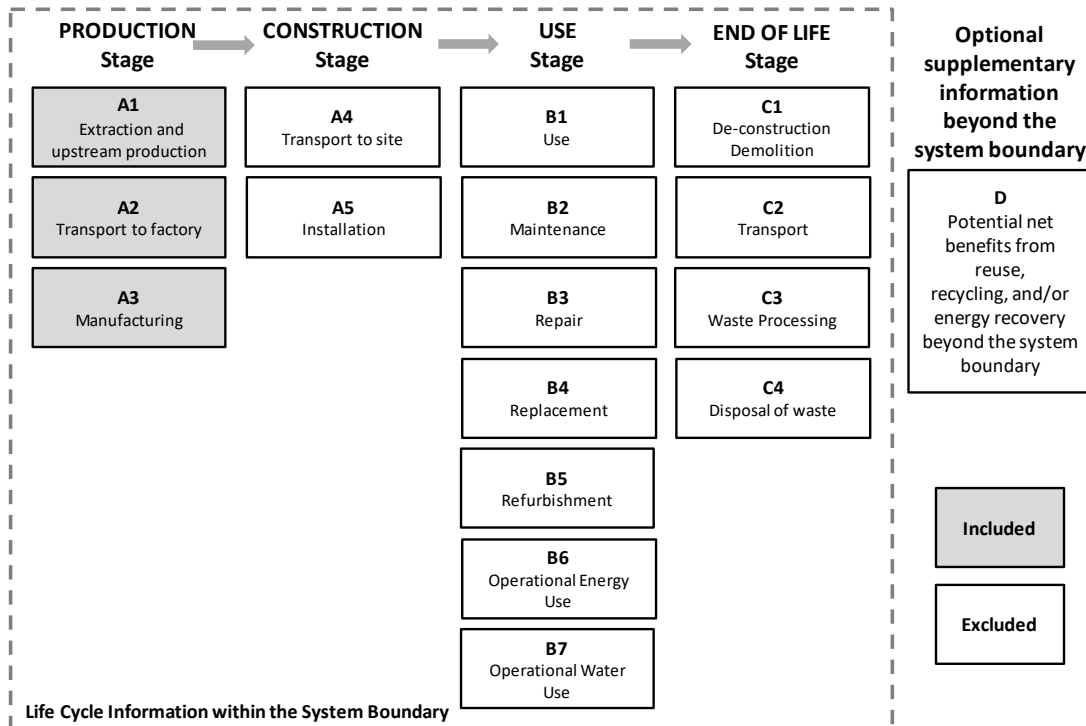


Figure 1 Common four life cycle stages and their information modules for construction products and the optional supplementary module [2]

The **Production stage** (modules A1 to A3) includes the following processes:

A1 Extraction and upstream production: Extraction and processing of input raw materials used in the production of standard, medium, high & ultra-high-density SFRMs, including fuels used in extraction and transport within the process.

A2 Transportation to factory: Transportation of input raw materials (including recovered materials) from extraction site or source to manufacturing facilities, including empty backhauls.

A3 Manufacturing: Manufacturing of the SFRMs, including all on-site energy and ancillary materials required and emissions to air, water and land and wastes produced. This also includes transportation from manufacturing site to landfill for on-site wastes, including empty backhauls and the waste disposal process. The A3 module includes grinding, mixing, blending, pneumatic conveying, high-speed auger packaging, lighting and heating, ventilation and air conditioning, operation of environmental equipment (baghouses and bin vents), on-site transportation (loading and unloading) and storage of SFRMs.

5 LIFE CYCLE INVENTORY

5.1 DATA COLLECTION, SOURCE AND CALCULATIONS

LCI data collection was based on a customized survey of all three GCPAT's SFRM manufacturing sites. All facility specific LCI data were weighted based on facility level total annual production to calculate the weighted average LCI profile for each product type (per 1,000 kg). Data calculation procedures follow ISO 14044. Per ISO 21930, 7.2.2 the net calorific value (lower heating value) of fuels is applied according to scientifically based and accepted values specific to the combustible material.

5.2 DATA QUALITY REQUIREMENTS AND ASSESSMENTS

A detailed description of collected data and the data quality assessment regarding the core PCR requirements and ISO 14044 is provided in the LCA report. Data quality is assessed based on its representativeness (technology coverage, geographic coverage, time coverage), completeness, consistency, reproducibility, transparency, and uncertainty (Table 4).

Table 4 Data Quality Requirements and Assessments

Data Quality Requirements	Description
Technology Coverage	Data represents the prevailing company technology in use in U.S. and Canada. Whenever available, for all upstream and core material and processes, North American typical or average industry LCI datasets were utilized. <i>Technological representativeness is characterized as "high".</i>
Geographic Coverage	The geographic region considered is U.S. and Canada. The geographic coverage of all LCI databases and datasets is given in the LCA background report. <i>Geographical representativeness is characterized as "high".</i>
Time Coverage	Activity data are representative as of 2019. - SFRM manufacturing process- primary data collected from 3 facilities: reference year 2019 (12 months); - In-bound/ out-bound transportation data- primary data collected from 3 facilities: reference year 2019 (12 months); - Generic data: the most appropriate LCI datasets were used as found in the US LCI Database, ecoinvent v.3.7.1 database, 2021. <i>Temporal representativeness is characterized as "high".</i>
Completeness	All relevant, specific processes, including inputs (raw, secondary, ancillary, and packaging materials, and energy flows) and outputs (emissions and production volume) were considered and modeled to provide a weighted average for the SFRM products of interest. The relevant background materials and processes were taken from the US LCI Database, ecoinvent v 3.7.1 LCI database, and modeled in SimaPro v9.2.0.2, 2021. The completeness of the cradle-to-gate process chain in terms of process steps is rigorously assessed for SFRM products of interest and documented in the LCA background report.



Data Quality Requirements	Description
Consistency	To ensure consistency, the LCI modeling of the production weighted input and output LCI data for the SFRM product of interest used the same LCI modeling structure across the 3 facilities, which consisted of input raw, secondary, ancillary, and packaging materials, energy flows, water resource inputs, product outputs, co-products, by-products, emissions to air, water and soil, and solid and liquid waste disposal. Crosschecks concerning the plausibility of mass and energy flows were continuously conducted. The LCA team conducted mass and energy balances at the facility level and selected process levels to maintain a high level of consistency.
Reproducibility	Internal reproducibility is possible since the data and the models are stored and available in <i>GCPAT_SFRM_LCI database</i> developed in SimaPro, 2021. A high level of transparency is provided throughout the report as the weighted average LCI profile is presented for each of the declared products as well as major upstream inputs. Key primary (manufacturer specific) and secondary (generic) LCI data sources are summarized in Annex C. External reproducibility is also possible as a high level of transparency is provided throughout the Project Report and LCI data and sources are also summarized.
Transparency	Activity and LCI datasets are transparently disclosed in the project report, including data sources.
Uncertainty	A <i>sensitivity check</i> was conducted to assess the reliability of the EPD results and conclusions by determining how they are affected by uncertainties in the data or assumptions on calculation of LCIA and energy indicator results. The sensitivity check includes the results of the <i>sensitivity analysis</i> and <i>Monte Carlo uncertainty analysis</i> both of which are summarized in the LCA report.

5.3 ALLOCATION AND CUT-OFF RULES

“Mass” was deemed as the most appropriate physical parameter for allocation used for the SFRMs manufacturing system to calculate the input energy flows (electricity, natural gas, and propane), packaging materials and waste flows per declared unit of 1,000 kg of SFRM. LCI modeling accounts for the plant specific fabrication yields in accordance with ISO 14044, 4.3.4.2.

Secondary materials such as hammermilled newsprint and post-industrial polystyrene are considered recovered materials. However, only the materials, water, energy, emissions, and other elemental flows associated with reprocessing, handling, sorting, and transportation from the generating industrial process to their use in the production process are considered. Any allocated burdens before reprocessing are allocated to the original product. Allocation related to transport are based on the mass of transported product.

The cut-off criteria as per ISO 21930, were followed for this EPD. All input/output data required were collected and included in the LCI modelling. No substances with hazardous and toxic properties that pose a concern for human health and/or the environment were identified in the framework of this EPD. Any data gaps for the reference year 2019 - e.g., packaging materials were filled in with plant generic data from previous years.



The Production Stage *excludes* the following processes:

- Capital goods and infrastructure;
- Human activity and personnel related activity (travel, furniture, office operations and supplies);
- Energy and water use related to company management and sales activities that may be located either within the factory site or at another location.

6 LIFE CYCLE ASSESSMENT

6.1 RESULTS OF THE LIFE CYCLE ASSESSMENT

This section summarizes the product stage life cycle impact assessment (LCIA) results including resource use and waste generated metrics based on the cradle-to-gate life cycle inventory inputs and outputs analysis. Table 5 presents the calculated results for each product density based on 1,000 kg (1 metric ton). *It is noted that LCIA results are relative expressions and do not predict impacts on category endpoints, the exceeding of thresholds, safety margins or risks [2], [3].*

Table 5 Production Stage (A1-A3), EPD Results for 1,000 kg standard, medium, high & ultra-high density SFRMs

Impact category and inventory indicators	Unit	Standard Density (min 15 pcf)	Medium Density (min 22 pcf)	High & Ultra High Density (min 40 pcf)
Global warming potential, GWP 100 ¹⁾ , AR5	kg CO ₂ eq	210	493	621
Ozone depletion potential, ODP ¹⁾	kg CFC-11 eq	1.2E-04	1.3E-04	1.4E-04
Smog formation potential, SFP ¹⁾	kg O ₃ eq	29.1	35.3	52.5
Acidification potential, AP ¹⁾	kg SO ₂ eq	1.4	1.9	2.6
Eutrophication potential, EP ¹⁾	kg N eq	0.33	0.67	0.89
ADP elements, CML ²⁾	kg Sb eq	1.0E-04	6.6E-04	1.8E-03
ADP surplus, TRACI ¹⁾	MJ surplus	515	607	683
Renewable primary resources used as an energy carrier (fuel), RPR _E ³⁾	MJ LHV	166.9	405.6	450.3
Renewable primary resources with energy content used as material, RPR _M ³⁾	MJ LHV	0	0	0
Non-renewable primary resources used as an energy carrier (fuel), NRPR _E ³⁾	MJ LHV	3,849	5,051	5,833
Non-renewable primary resources with energy content used as material, NRPR _M ³⁾	MJ LHV	0	0	0
Secondary materials, SM ³⁾	kg	71	90	63
Renewable secondary fuels, RSF ³⁾	MJ LHV	0.080	17	23
Non-renewable secondary fuels, NRSF ³⁾	MJ LHV	0.77	167	218
Recovered energy, RE ³⁾	MJ LHV	0	0	0
Consumption of freshwater, FW ³⁾	m ³	0.31	0.62	0.64
Hazardous waste disposed, HWD ³⁾	kg	0.035	0.027	0.009
Non-hazardous waste disposed, NHWD ³⁾	kg	19.9	116.0	143.5
High-level radioactive waste, conditioned, to final repository, HLRW ³⁾	m ³	9.8E-07	9.8E-07	1.0E-06
Intermediate- and low-level radioactive waste, conditioned, to final repository, ILLRW ³⁾	m ³	2.8E-06	3.3E-06	5.0E-06
Components for re-use, CRU ³⁾	kg	0	0	0
Materials for recycling, MR ³⁾	kg	0	0	0
Materials for energy recovery, MER ³⁾	kg	0	0	0
Recovered energy exported from the product system, EE ³⁾	MJ LHV	0.0029	0.62	0.81
Global warming potential - biogenic, GWP-100 bio ³⁾⁴⁾		1.1E-03	0.23	0.30
Emissions from calcination ³⁾⁴⁾		0.71	152.3	200.0



Impact category and inventory indicators	Unit	Standard Density (min 15 pcf)	Medium Density (min 22 pcf)	High & Ultra High Density (min 40 pcf)
Emissions from combustion of waste from renewable sources ³⁾⁴⁾		3.00E-04	0.064	0.085
Emissions from combustion of waste from non-renewable sources ³⁾⁴⁾		0.072	15.5	20.3
Removals associated with biogenic carbon content of the bio-based product ³⁾		-98.0	-66.2	-41.5
Removals associated with biogenic carbon content of the bio-based packaging ³⁾		-40.9	-40.9	-40.9

Table Notes:

¹⁾ Calculated as per U.S EPA TRACI 2.1, v1.05, SimaPro v 9.2.0.2. GWP₁₀₀, excludes biogenic CO₂ removals and emissions; 100-year time horizon GWP factors are provided by the IPCC 2013 Fifth Assessment Report (AR5), TRACI 2.1, with AR5, v1.05.

²⁾ Calculated as per CML-IA Baseline V3.05, SimaPro v 9.2.0.2.

³⁾ Calculated as per ACLCA ISO 21930 Guidance, respective sections 6.2 to 10.8.

⁴⁾ Applicable for Portland cement only, used in manufacturing of the GCPAT SFRM [11].

6.2 INTERPRETATION

The cradle-to-gate manufacture of **standard density SFRM** embodies about 4 GJ of primary energy (LHV) and emits 210 kg CO₂ eq of greenhouse gases per ton of product. Around 96% of the total primary energy input is derived from non-renewable primary energy resources. Across the three standard density production information modules, Module A1 extraction and upstream production contributes the largest share of the LCIA and energy indicator results – accounting for between 60% (NRPR_E) and 54% (GWP-100) of the potential environmental burdens. Module A3 Manufacturing is generally the second largest contributor to the overall potential environmental impacts – accounting for 32% and 29% of GWP and non-renewable energy use, respectively. Except for acidification (26%) and smog potential impacts (35%), Module A2 Transportation is generally a minor contributor (<15%) to the overall potential environmental impacts of standard density SFRM production.

The cradle-to-gate manufacture of **medium density SFRM** embodies about 5.5 GJ of primary energy (LHV) and emits 493 kg CO₂ eq of greenhouse gases per ton of product. About 93% of the total primary energy input is derived from non-renewable primary energy resources. Across the three medium density production information modules, Module A1 extraction and upstream production contributes the largest share of the LCIA and energy indicator results – accounting for 82% (GWP-100), 72% (NRPRE) and over 50% of both acidification and smog formation burdens. Unlike standard density SFRM, Module A3 Manufacturing is a more minor contributor to the overall potential environmental impacts of medium density SFRM – accounting for 17% of NRPR_E and 9% of GWP-100. Module A2 Transportation is a significant contributor to SFP (37%), AP (27%) and GWP (9%) to the overall potential environmental impacts of medium density SFRM manufacture.

The cradle-to-gate manufacture of **high and ultra-high density SFRM** embodies about 6.3 GJ of primary energy (LHV) and emits 621 kg CO₂ eq of greenhouse gases per ton of product. Almost 93% of the total primary energy input is derived from non-renewable primary energy resources. Across the three high and ultra-high density production information modules, Module A1 extraction and upstream production contributes the largest share of the key LCIA and energy indicator results – accounting for 80% (GWP-100), 67% (NRPRE) and 78% of eutrophication potential burden. Similar to medium density SFRM, Module A3 Manufacturing is a more minor contributor to the overall potential environmental impacts of high and ultra-high density SFRM – accounting for 15% of NRPRE and 13% of GWP-100. Module A2 Transportation is a significant contributor to SFP (53%), AP (39%) and GWP (9%) to the overall potential environmental impacts of high and ultra-high density SFRM manufacture.

7 ADDITIONAL ENVIRONMENTAL INFORMATION

Standard, medium and high & ultra-high density SFRMs use between 2% to 7% recovered materials (hammermilled newsprint and post-industrial polystyrene).

8 DECLARATION TYPE

GCPAT SFRM EPD is categorized as follows:

- A corporate specific product EPD, averaged across the manufacturer's plants.

This declaration presents a weighted average EPD for three SFRM North American facilities operated by GCPAT. Product activities covered include the raw material supply, transport and manufacturing (modules A1 to A3). The declaration is intended for Business-to-Business (B-to-B) communication.

9 DECLARATION COMPARABILITY LIMITATION STATEMENT

- Only EPDs prepared from cradle-to-grave life cycle results and based on the same function, RSL, quantified by the same functional unit, and meeting all the conditions for comparability listed in ISO 14025:2006 and ISO 21930:2017 can be used to comparison between products.



10 EPD EXPLANATORY MATERIAL

For any explanatory material, regarding this EPD please contact the program operator.

ASTM International

Environmental Product Declarations

100 Barr Harbor Drive,

West Conshohocken,

PA 19428-2959,

<http://www.astm.org>

11 REFERENCES

1. ISO 14025:2006 Environmental labeling and declarations - Type III environmental declarations - Principles and procedures.
2. ISO 21930:2017 Sustainability in buildings and civil engineering works - Core rules for environmental product declarations of construction products and services.
3. ISO 14040:2006/Amd 1:2020 Environmental management - Life cycle assessment - Principles and framework.
4. ISO 14044:2006/Amd1:2017/Amd2:2020 Environmental management - Life cycle assessment - Requirements and guidelines.
5. ASTM Program Operator Rules. Version: 8.0, Revised 04/29/20.
6. ISO 14021:2016 Environmental labels and declarations - Self-declared environmental claims (Type II environmental labelling).
7. PRé 2019. SimaPro LCA Software v9.2.0.2, 2021, <https://simapro.com/>
8. LEED v4, *Building Design and Construction Guide (BD+C), MR Credit: Building Product Disclosure and Optimization – Environmental Product Declarations, Option 2 Multi-attribute optimization* (1 point). <https://www.usgbc.org/node/2616376?return=/credits/new-construction/v4/material-%26amp%3B-resources>.
9. LEED v4.1, *Building Design and Construction Guide (BD+C), MR Credit: Building Product Disclosure and Optimization – Environmental Product Declarations, Option 2 Multi-attribute optimization* (1 point). <https://leeduser.buildinggreen.com/credit/NC-v4.1/MRC2#tab-credit-language>.
10. ACLCA 2019, Guidance to Calculating Non-LCIA Inventory Metrics in Accordance with ISO 21930:2017. The American Centre for Life Cycle Assessment. May 2019. <https://aclca.org/aclca-iso-21930-guidance/>
11. PCA 2021, EPD, Portland Cement- Industry-wide. <https://www.astm.org/products-services/certification/environmental-product-declarations/epd-pcr.html>
12. Athena 2021, A Cradle-to-Gate Life Cycle Assessment of GCP Applied Technologies Standard, Medium and High & Ultra High-Density Spray-applied Fire-Resistive Materials (SFRMs), Final Report.

ASTM International
West Conshohocken, PA
www.astm.org

Date of issue: 04.15.2022
Period of validity: 5 years
Declaration #: EPD 060

**MONOKOTE® MK-6HY
DECLARE LABEL**

Declare.

Monokote MK-6/HY GCP

Final Assembly: Santa Ana, California, USA; Ajax, Ontario, CA;
Cheongneung-daero, Incheon, Korea

Life Expectancy: Life of Structure Year(s)

Embodied Carbon: 210 kg CO₂eq

Declared Unit: 1,000 kg

End of Life Options: Landfill (100%)

Ingredients:

Sulfuric acid, calcium salt (1:1); Pulp, cellulose; Polystyrene;
Calcium Carbonate; Quartz

Living Building Challenge Criteria: Compliant

I-13 Red List:

- | | |
|---|-----------------------------|
| ☒ LBC Red List Free | % Disclosed: 100% at 100ppm |
| ☐ LBC Red List Approved | VOC Content: 0 g/L |
| ☐ Declared | |

I-10 Interior Performance: CDPH Standard Method v1.2-2017

I-14 Responsible Sourcing: Not Applicable

WRG-0001
EXP. 01 MAY 2027
Original Issue Date: 2017

MANUFACTURER RESPONSIBLE FOR LABEL ACCURACY
INTERNATIONAL LIVING FUTURE INSTITUTE™ living-future.org/declare

Volatile Organic Compounds (VOCs) Content Report



VTEC Laboratories, Inc.
212 Manida Street, Bronx, NY 10474
Office: 718-542-8248 *** FAX: 718-542-8759
Neil@VTECLABS.com // jerry@vteclabs.com

JOB ID: V100-7716A // GC Applied Technologies; 104 W Lake Victoria Circle, DeLand, FL 32724
ATTN: Chad Johnson // TEL: 617-498-3800 // chad.johnson@gcpat.com
CC: John Dalton // TEL: n/a // john.a.dalton@gcpat.com

SAMPLE ID: Three (3) submitted loose, grey Fibrous materials identified as:
Monokote Fireproofing MK-6s, MK-6HY and MK-10/HB

SCOPE: Determination of VOC Content in submitted Sample materials according to EPA Method-24 with LOD @ 110°C for TOTAL Volatiles and K-F Moisture analysis and ASTM D3960 by GC-MS for Individual Volatile Organic compounds (VOCs)

SUBMISSION DATE: 18-Aug2023

REPORT DATE: 29-Aug-2023

ANALYZED BY: Dr. Jerry DeMenna, Director of Analytical Research

PROCEDURES:

[1] Evaluation of TOTAL Volatiles (Organics, less Water) per ASTM D2369 / EPA Method-24.

[2] Determination of specific VOCs by GC-MS per ASTM D3960 / MilSpec 4.5.1.4

All Instrumentation used is ISO-9000 Certified & calibrations done with NIST-Traceable Reference Standards.

DATA Results: Results of the duplicate EPA Method-24 and ASTM D3960 Testing. Data is expressed as Weight Percent (%wt) VOCs in the Original Liquid Sample material =

<u>Sample ID</u>	<u>TOTAL ASTM D2369 VOCs</u>	<u>D3960 VOCs</u>	<u>AVG VOC Content</u>
<i>MK-6s</i>	0.23%wt VOC	0.28%wt VOC	<u>0.26%wt VOC</u>
<i>MK-6HY</i>	0.25%wt VOC	0.33%wt VOC	<u>0.29%wt VOC</u>
<i>MK-10/HB</i>	0.24%wt VOC	0.31%wt VOC	<u>0.28%wt VOC</u>
<u>Limit of Detection (LOD)</u>	0.05%wt VOC	0.001%wt VOC	n/a

CONCLUSION:

This testing shows these materials are very similar and had less than 1%wt VOC for classification as a VOC-Free material, depending on the application of these Products.

End Report / gjdm / 29Aug23

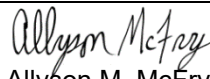
Dr. Jerry DeMenna
Laboratory Mgr.

DISCLAIMER: This is a factual report of the results obtained from the Analytical Laboratory testing of the aforementioned products. These results may be considered in application to the specific products tested in this report, and should not be construed as representative of the composition of other, similar products from the manufacturer. This report shall not be considered a recommendation or disapprobation by VTEC Laboratories, Inc., of the materials tested. This report may be used for obtaining product acceptance and for general characterization of the materials, but shall not be used in any advertising situations. VTEC Laboratories, Inc. shall not be liable for any loss or damages resulting from the use of the data in this report.

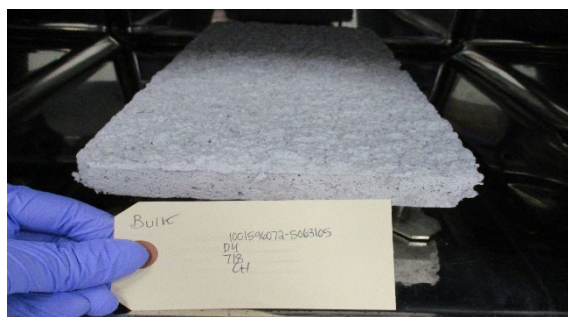
NOTICE: VTEC Laboratories, Inc. shall not be liable for any loss or damages resulting from the use of the data in this report; in excess of the invoice. The information in this report pertains to this sample(s) only. This report shall not be interpreted to be any form of warranty, either expressed or implied, as to the suitability or fitness of said sample(s) for such uses and/or applications, as the party contracting for the report may apply to such sample(s).

*** *Your One-Stop Source for all Chemical, Physical and Combustion Testing!* ***

Volatile Organic Compounds (VOCs) Emissions Report

INDOOR AIR QUALITY EVALUATION FOLLOWING THE REQUIREMENTS OF CDPH/EHLB/STANDARD METHOD		
Product Description	Monokote MK-6/HY* *customer attests the tested product is representative of the formulations MK-6/GF, MK-6/HY, MK-10/HB, Extended Set, MK-10/HB Extended Set, Z-3306/G, Retroguard RG. Alternative products were not reviewed by UL.	
Customer Information	GCP APPLIED TECHNOLOGIES INC JOHN DALTON FIRE OPERATING UNIT 2325 LAKEVIEW PKWY, STE 450 ALPHARETTA GA 30009	
Testing Laboratory	UL Environment - Marietta, 2211 Newmarket Parkway, Marietta, GA 30067-9399 USA	
Product Category	Insulation	
Date Received	June 2, 2022	
Test Description	The product was received by UL Environment as packaged and shipped by the customer. The package was visually inspected and stored in a controlled environment immediately following sample check-in. Just prior to loading, the product was unpackaged and placed in a metal tray to expose the top surface only. The sample was placed inside the environmental chamber and tested according to the specified protocol.	
Test Date	June 24, 2022 – July 8, 2022	
Product Area Exposed	one-sided area = 0.0934 m ²	
Environmental Chamber ID and Volume	SD4 - 0.0860 m ³	
Product Loading Ratio	1.09 m ² /m ³	
Test Chamber Conditions	Air change rate: 1.00 ± 0.05 1/h Inlet air flow rate: 0.086 ± 0.004 m ³ /h	Temperature: 22.5°C - 23.6°C Relative Humidity: 50% RH ± 5% RH
Test Method	CDPH - CA Section 01350 <i>Standard Method for the Testing and Evaluation of Volatile Organic Chemical Emissions from Indoor Sources using Environmental Chambers</i> Version 1.2.	
Authorized by	 Allyson M. McFry Chemistry Laboratory Director	
*The temperature range specification is 23°C ± 1°. The actual temperature range listed above may vary slightly. If the range is outside this specification, data was reviewed to ensure a negative impact did not occur.		
This test is accredited and meets the requirements of ISO/IEC 17025 as verified by ANSI National Accreditation Board. Refer to certificate and scope of accreditation AT-1297.		

PHOTOGRAPH OF SAMPLE



RESULTS SUMMARY

Product Description		Monokote MK-6/HY* *customer attests the tested product is representative of the formulations MK-6/GF, MK-6/HY, MK-10/HB, Extended Set, MK-10/HB Extended Set, Z-3306/G, Retroguard RG. Alternative products were not reviewed by UL.			
Environment	Product Usage	Product Surface Area	Room Volume	Ventilation Rate (ACH)	Product Compliance?
Classroom	ceiling	89.2 m ²	231 m ³	0.82	Yes
Office	ceiling	11.1 m ²	30.6 m ³	0.68	Yes

PROJECT DESCRIPTION

The product was monitored for emissions of TVOC, individual VOCs, formaldehyde and other aldehydes over the 96-hour test period. Measurements were made and predicted exposures were calculated according to the CA Section 01350 protocol. As specified in this protocol, the results at 96 hours, after 10 days of conditioning, were compared to ½ (one-half) the current Chronic Reference Exposure Levels (CRELs), as adopted from the California OEHHA list. All identified VOCs were also compared to the California-EPA OEHHA Proposition 65 list and the California-EPA Air Resource Board list of Toxic Air Contaminants (TACs).

Report Outline:

Table 1	Comparison of Data To Method Requirements
Table 2	Chamber Concentrations and Emission Factors
Table 3	Most Abundant Compounds
Table 4	VOC Predicted Air Concentrations And Regulatory Information
Chain of Custody	Chain of Custody

Download more information regarding UL's technical references and resources, product evaluation methodologies information, quality control program, and environmental chamber evaluations from our website [click here](#) or <https://www.ul.com/offering/greenguard-certification>

For RSD, Quality Assurance Report or other quality documents, [Request](#) here or contact ULE.

TABLE 1

Product Description		Monokote MK-6/HY* *customer attests the tested product is representative of the formulations MK-6/GF, MK-6/HY, MK-10/HB, Extended Set, MK-10/HB Extended Set, Z-3306/G, Retroguard RG. Alternative products were not reviewed by UL.					
COMPARISON OF DATA TO METHOD REQUIREMENTS AT 96 HOURS FOLLOWING 10 DAYS OF CONDITIONING							
Compound	CAS Number	½ CREL (µg/m³)	Chamber Concentration (µg/m³)	Emission Factor†† (µg/m²•hr)	Classroom Predicted Concentration (µg/m³)**	Office Predicted Concentration (µg/m³)**	Meets ½ CREL? (Classroom/Office)
Acetaldehyde	75-07-0	70	BQL	BQL	BQL	BQL	Yes
Benzene	71-43-2	1.5	BQL	BQL	BQL	BQL	Yes
Carbon disulfide	75-15-0	400	BQL	BQL	BQL	BQL	Yes
Carbon tetrachloride	56-23-5	20	BQL	BQL	BQL	BQL	Yes
Chlorobenzene	108-90-7	500	BQL	BQL	BQL	BQL	Yes
Chloroform	67-66-3	150	BQL	BQL	BQL	BQL	Yes
Dichlorobenzene (1,4-)	106-46-7	400	BQL	BQL	BQL	BQL	Yes
Dichloroethylene (1,1)	75-35-4	35	BQL	BQL	BQL	BQL	Yes
Dimethylformamide (N,N-)	68-12-2	40	BQL	BQL	BQL	BQL	Yes
Dioxane (1,4-)	123-91-1	1,500	BQL	BQL	BQL	BQL	Yes
Epichlorohydrin	106-89-8	1.5	BQL	BQL	BQL	BQL	Yes
Ethylbenzene	100-41-4	1,000	BQL	BQL	BQL	BQL	Yes
Ethylene glycol	107-21-1	200	BQL	BQL	BQL	BQL	Yes
Ethylene glycol monoethyl ether acetate	111-15-9	150	BQL	BQL	BQL	BQL	Yes
Ethylene glycol monoethyl ether	110-80-5	35	BQL	BQL	BQL	BQL	Yes
Ethylene glycol monomethyl ether acetate	110-49-6	45	BQL	BQL	BQL	BQL	Yes
Ethylene glycol monomethyl ether	109-86-4	30	BQL	BQL	BQL	BQL	Yes
Formaldehyde	50-00-0	9.0***	BQL	BQL	BQL	BQL	Yes

Product Description		Monokote MK-6/HY* *customer attests the tested product is representative of the formulations MK-6/GF, MK-6/HY, MK-10/HB, Extended Set, MK-10/HB Extended Set, Z-3306/G, Retroguard RG. Alternative products were not reviewed by UL.					
COMPARISON OF DATA TO METHOD REQUIREMENTS AT 96 HOURS FOLLOWING 10 DAYS OF CONDITIONING							
Compound	CAS Number	½ CREL (µg/m³)	Chamber Concentration (µg/m³)	Emission Factor†† (µg/m²•hr)	Classroom Predicted Concentration (µg/m³)**	Office Predicted Concentration (µg/m³)**	Meets ½ CREL? (Classroom/ Office)
Hexane (n-)	110-54-3	3,500	BQL	BQL	BQL	BQL	Yes
Isophorone	78-59-1	1,000	BQL	BQL	BQL	BQL	Yes
Isopropanol	67-63-0	3,500	BQL	BQL	BQL	BQL	Yes
Methyl chloroform	71-55-6	500	BQL	BQL	BQL	BQL	Yes
Methyl t-butyl ether	1634-04-4	4,000	BQL	BQL	BQL	BQL	Yes
Methylene chloride	75-09-2	200	BQL	BQL	BQL	BQL	Yes
Naphthalene	91-20-3	4.5	BQL	BQL	BQL	BQL	Yes
Phenol	108-95-2	100	BQL	BQL	BQL	BQL	Yes
Propylene glycol monomethyl ether	107-98-2	3,500	BQL	BQL	BQL	BQL	Yes
Styrene	100-42-5	450	11.5	10.5	4.9	5.6	Yes
Tetrachloroethylene (perchloroethylene)	127-18-4	17.5	BQL	BQL	BQL	BQL	Yes
Toluene	108-88-3	150	BQL	BQL	BQL	BQL	Yes
Trichloroethylene	79-01-6	300	BQL	BQL	BQL	BQL	Yes
Vinyl acetate	108-05-4	100	BQL	BQL	BQL	BQL	Yes
Xylenes (m-, o-, p-)	1330-20-7	350	2.1	1.9	0.9	1.0	Yes

BQL denotes below quantifiable level of 0.04 µg for individual VOCs, with the exceptions benzene and epichlorohydrin which have a QL of 0.02 µg, based on a standard 18 L air collection volume.

^{††}The emission factor (EF) is calculated from the chamber concentration (CC), the chamber air change rate (N_C), the chamber volume (V_C), and the product area exposed in the chamber (A_C) as: $EF = (CC \cdot V_C \cdot N_C) / A_C$.

^{**}The predicted building exposure concentration (BC) is calculated from the emission factor (EF), the building air change rate (N_B), the building room volume (V_B), and the product area exposed in the building room (A_B) as: $BC = (EF \cdot A_B) / (V_B \cdot N_B)$. For more information on Predicted Concentration modeling parameters, [click here](#).

^{***}Guidance value per CA Standard Method

TABLE 2

Product Description	Monokote MK-6/HY* *customer attests the tested product is representative of the formulations MK-6/GF, MK-6/HY, MK-10/HB, Extended Set, MK-10/HB Extended Set, Z-3306/G, Retroguard RG. Alternative products were not reviewed by UL.	
CHAMBER CONCENTRATIONS AND EMISSION FACTORS FOR TVOC AND FORMALDEHYDE AT 24, 48, AND 96 HOURS FOLLOWING 10 DAYS OF CONDITIONING		
Elapsed Exposure Hour After 10 Days Conditioning	Chamber Concentration (µg/m³)	Emission Factor†† (µg/m²•hr)
TVOC†		
24	52.5	48.4
48	51.8	47.6
96	38.4	35.4
Formaldehyde‡		
24	BQL	BQL
48	BQL	BQL
96	BQL	BQL

BQL denotes below quantifiable level of 2 µg/m³.

Exposure hours are nominal (± 1 hour).

[†]Defined as the sum of those VOCs that elute between the retention times of n-hexane (C₆) and n-hexadecane (C₁₆) on a non-polar capillary GC column quantified based on a toluene response factor.

[‡]Compound identified and quantified by DNPH derivitization and HPLC/UV analysis.

^{††}The emission factor (EF) is calculated from the chamber concentration (CC), the chamber air change rate (N_c), the chamber volume (V_c), and the product area exposed in the chamber (A_c) as: $EF = (CC \cdot V_c \cdot N_c) / A_c$.

TABLE 3

Product Description		Monokote MK-6/HY* *customer attests the tested product is representative of the formulations MK-6/GF, MK-6/HY, MK-10/HB, Extended Set, MK-10/HB Extended Set, Z-3306/G, Retroguard RG. Alternative products were not reviewed by UL.			
TEN MOST ABUNDANT IDENTIFIED INDIVIDUAL VOLATILE ORGANIC COMPOUNDS (VOCs) AND/OR ALDEHYDES AT 96 HOURS FOLLOWING 10 DAYS OF CONDITIONING					
CAS Number	Compound	Chamber Concentration (µg/m³)	Emission Factor†† (µg/m²•hr)	Calculated Predicted Exposure Concentration** (µg/m³)	
				Classroom	Office
---	TVOC‡‡	38.4	35.4	16.7	18.9
100-42-5	Styrene†	11.5	10.5	4.9	5.6
98-86-2	Acetophenone (Ethanone, 1-phenyl)*†	7.2	6.6	3.1	3.5
100-52-7	Benzaldehyde‡	3.6	3.3	1.6	1.8
104-76-7	1-Hexanol, 2-ethyl†	2.8	2.6	1.2	1.4
5989-27-5	D-Limonene*	2.7	2.5	1.2	1.3
66-25-1	Hexanal‡	2.7	2.5	1.2	1.3
41446-64-4	6-Tetradecene, (E)-*	2.1	2.0	0.9	1.1
1330-20-7	Xylenes (Total)†	2.1	1.9	0.9	1.1

Exposure hours are nominal (± 1 hour).

VOC data obtained by scanning GC/MS; identification of compound made by retention time and mass spectral characteristics.

[†]Quantified using multipoint authentic standard curve. Other VOCs quantified relative to toluene.

^{*}Identification based on NIST mass spectral database only.

[‡]Compound identified and quantified by DNPH derivitization and HPLC/UV analysis.

^{††}The emission factor (EF) is calculated from the chamber concentration (CC), the chamber air change rate (N_C), the chamber volume (V_C), and the product area exposed in the chamber (A_C) as: $EF = (CC \cdot V_C \cdot N_C) / A_C$.

^{‡‡}Defined as the sum of those VOCs that elute between the retention times of n-hexane (C₆) and n-hexadecane (C₁₆) on a non-polar capillary GC column quantified based on a toluene response factor.

^{**}The predicted building exposure concentration (BC) is calculated from the emission factor (EF), the building air change rate (N_B), the building room volume (V_B), and the product area exposed in the building room (A_B) as: $BC = (EF \cdot A_B) / (V_B \cdot N_B)$. For more information on Predicted Concentration modeling parameters, [click here](#).

TABLE 4

Product Description		Monokote MK-6/HY* *customer attests the tested product is representative of the formulations MK-6/GF, MK-6/HY, MK-10/HB, Extended Set, MK-10/HB Extended Set, Z-3306/G, Retroguard RG. Alternative products were not reviewed by UL.						
VOC PREDICTED AIR CONCENTRATIONS AND REGULATORY INFORMATION AT 96 HOURS FOLLOWING 10 DAYS OF CONDITIONING								
CAS Number	Compound	Chamber Concentration (µg/m³)	Emission Factor†† (µg/m²•hr)	Predicted Exposure Concentration** (µg/m³)		✓ Indicates Presence On List		
				Classroom	Office	CA PROP 65	CA AIR TOXIC	CREL
98-86-2	Acetophenone (Ethanone, 1-phenyl)†	7.2	6.6	3.1	3.5		✓(IVA)	
98-82-8	Benzene, 1-methylethyl (Cumene)	2.2	2.0	0.9	1.1	✓(1)	✓(IVA)	
100-42-5	Styrene†	11.5	10.5	4.9	5.6	✓(1)	✓(IIA; III)	✓
1330-20-7	Xylenes (Total)†	2.1	1.9	0.9	1.0		✓(IIA)	✓

[†]Quantified using multipoint authentic standard curve. Other VOCs quantified relative to toluene.

[‡]Compound identified and quantified by DNPH derivitization and HPLC/UV analysis.

^{††}The emission factor (EF) is calculated from the chamber concentration (CC), the chamber air change rate (N_c), the chamber volume (V_c), and the product area exposed in the chamber (A_c) as: $EF = (CC \cdot V_c \cdot N_c) / A_c$.

^{**}The predicted building exposure concentration (BC) is calculated from the emission factor (EF), the building air change rate (N_B), the building room volume (V_B), and the product area exposed in the building room (A_B) as: $BC = (EF \cdot A_B) / (V_B \cdot N_B)$. For more information on Predicted Concentration modeling parameters, [click here](#).

CAL Prop. 65: California Health and Welfare Agency, Proposition 65 Chemicals

1 = known to cause cancer

2 = known to cause reproductive toxicity

CAL Toxic Air Contaminant:

I) Substances identified as Toxic Air Contaminants, known to be emitted in California, with a full set of health values reviewed by the Scientific Review Panel.

IIA) Substances identified as Toxic Air Contaminants, known to be emitted in California, with one or more health values under development by the Office of Environmental Health Hazard Assessment for review by the Scientific Review Panel.

IIB) Substances NOT identified as Toxic Air Contaminants, known to be emitted in California, with one or more health values under development by the Office of Environmental Health Hazard Assessment for review by the Scientific Review Panel.

III) Substances known to be emitted in California, and are NOMINATED for development of health values or additional health values.

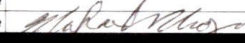
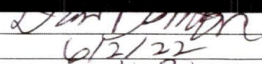
IVA) Substance identified as Toxic Air Contaminants, known to be emitted in California, and are TO BE EVALUATED for entry into Category III.

IVB) Substance NOT identified as Toxic Air Contaminants, known to be emitted in California, and are TO BE EVALUATED for entry into Category III.

V) Substance identified as Toxic Air Contaminants, and NOT KNOWN TO BE EMITTED from stationary source facilities in California based on information from the AB 2588 Air Toxic "Hot Spots" Program and the California Toxic Release Inventory.

VI) Substances identified as Toxic Air Contaminants, NOT KNOWN TO BE EMITTED from stationary source facilities in California, and are active ingredients in pesticides in California.

Product Description	Monokote MK-6/HY* *customer attests the tested product is representative of the formulations MK-6/GF, MK-6/HY, MK-10/HB, Extended Set, MK-10/HB Extended Set, Z-3306/G, Retroguard RG. Alternative products were not reviewed by UL.
CHAIN OF CUSTODY	

INTERNAL Use Only		5063105			
Project #	1001596072	Description	5063105 Monokote MK-6/HY* *customer attests the tested product is representative of the formulations MK-6/GF, MK-6/HY, MK-10/HB, Extended Set, MK-10/HB Extended Set, Z-3306/G, Retroguard RG. Alternative products were not reviewed by UL.		
Product #	5063105	Customer	GCP Applied Technologies Inc		
	14312852	Received Date:	LabWare Project No: 1001596072 Order No.: 14312852 2022-JUN-16 11:50:11 Oracle Project No.:		
Task Line	1.1	UL BU			
1 of 1				1 of 3	
☐ Rush Request - Subject to upcharge. Customer must confirm with  CUWFB1066					
GREENGUARD Test Information					
Test Type	☐ Certification Test • Annual/Initial Year _____ ☐ Quarterly Test • Year _____ Quarter _____		☐ Out-of-Scope Test ☐ Profile Study Test		
Service Line	☐ GREENGUARD ☐ GREENGUARD GOLD ☐ Other <u>CDPH v1.2</u>				
Test Group					
Product Category					
Application	☐ Floor/Ceiling ☐ Panel ☐ Wall ☐ Work Surface ☐ Other: _____				
Wet Products Only	Coverage Rate		Density	Specific Gravity	
Product and Company Information					
Product Description	<u>Monokote MK-6-HY</u> Monokote MK-6/HY* *Customer attests the tested product is representative of the formulations MK-6/GF, MK-6/HY, MK-10/HB, Extended Set, MK-10/HB Extended Set, Z-3306/G, Retroguard RG. Alternative products were not reviewed by UL.				
Manufacture ID#					
Company Name	GCP	Date Manufactured	04/23/2022		
Address	2325 Lakewood Parkway Alpharetta GA 30009	Contact Name	Ziondale Plant		
		Job Title			
		Contact Phone			
Contact Email					
Collection Information					
Collector Name	Mike Morgan		Date Collected	05/04/2022	
Collector Phone			Time Collected	mixed with water	
Collector Signature			Collection Location	and sprayed	
Shipping Information					
Carrier	Fed Ex				
Shipper Name			Date Shipped	05/25/2022	
Shipper Phone			Time Shipped		
Shipper Signature			Air Bill #	7769 4576 8594	
Sample Submitted to					
☒ UL Environment (Marietta) 2211 Newmarket Pkwy Suite 106 Marietta, GA 30067, USA	☐ UL Verification Services (Guangzhou) Building A1, 3F, Nansha Science and Technology Innovation Ctr. No. 25, South Huanan Avenue, Nansha District, Guangzhou 511458, China		☐ UL International Italia S.r.l. ATTN: IAQ Laboratory Via Europa, 9 I - 22060 - Cabiate (Como), Italia		☐ UL VS (Vietnam) Co., Ltd. Lot C5, Conurbation 2, Street K1, Cat Lai Industrial Zone Thanh My Loi Ward, District 2 Ho Chi Minh City, Vietnam
Post Testing Sample Disposition (Sample will be disposed of 30 days after report is issued if information below is not provided)					
Return Shipping Co.			Customer Shipping Acct #		
Internal Use Only - Receiving Information					
Receiver Name	JTB		Receiver Signature		
Condition Upon Arrival	☒ Acceptable ☐ Not Acceptable		Receive Date	6/2/22	
Condition Notes			Receive Time	14:30	
Completed By	Based On		Date		



VOC EMISSION RESULTS COMPARISON TO STANDARD

Standard referenced: CDPH/EHLB/Standard Method V1.2 (January 2017) "Standard Method for the Testing and Evaluation of Volatile Organic Chemical Emissions from Indoor Sources Using Environmental Chambers" (aka CA Section 01350).

PRODUCT SAMPLE INFORMATION

Manufacturer	GCP Applied Technologies Inc
Product Description	Monokote MK-6/HY* *customer attests the tested product is representative of the formulations MK-6/GF, MK-6/HY, MK-10/HB, Extended Set, MK-10/HB Extended Set, Z-3306/G, Retroguard RG. Alternative products were not reviewed by UL.
Product Type	Insulation
UL Sample Identification	1001596072-5063105
Manufactured Date	April 23, 2022
Test Completed Date	July 8, 2022
UL Report #	1001596072-5063105
Report Date	July 13, 2022

TEST RESULTS COMPARISON TO STANDARD CRITERIA

Environment	Classroom		Office	
Surface Area	89.2 m ²		11.1 m ²	
	Criterion	Meets?	Criterion	Meets?
Individual VOC	≤ ½ CREL	Yes	≤ ½ CREL	Yes
Formaldehyde	≤ 9.0 µg/m ³	Yes	≤ 9.0 µg/m ³	Yes

Environment	Classroom	Office
Surface Area	89.2 m ²	11.1 m ²
TVOC	0.5 mg/m ³ or less	0.5 mg/m ³ or less

TVOC comparison is based on LEED BD+C: New Construction v4 (LEED v4), Indoor environmental quality (EQ) category/Low-emitting materials credit/Emissions and content requirements/General emissions evaluation.

<http://www.usgbc.org/node/2614095?return=/credits/new-construction/v4/indoor-environmental-quality>

Authorized by	 Allyson McFry Chemistry Laboratory Manager
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Complete testing and data results are presented in UL Environment Report

Disclaimer: This Comparison affirms that: 1) the product sample was tested according to the referenced standard; 2) the measured VOC emissions were evaluated for the defined exposure scenario(s); and 3) if so indicated above that the results meet the criteria of the referenced standard(s). UL Environment did not select the samples, determine if the samples were representative of production samples, witness the production of test samples, or were we provided with information relative to the formulation or identification of component materials used in the test samples. The test results apply only to the actual samples tested. The issuance of this Comparison in no way implies Listing, Classification or Recognition by UL and does not authorize the use of UL Listing, Classification or Recognition Marks or any other reference to UL on the product or system. UL Environment authorizes the above named company to reproduce this Comparison provided it is reproduced in its entirety. The name, brand or marks of UL cannot be used in any packaging, advertising, promotion or marketing relating to the data in this Comparison, without UL's prior written permission. UL, its subsidiaries, employees and agents shall not be responsible to anyone for the use or nonuse of the information contained in this Comparison, and shall not incur any obligation or liability for damages, including consequential damages, arising out of or in connection with the use of, or inability to use, the information contained in this Comparison.



UL Restricted Materials Conformity Report

Restricted Materials Conformity Report

CETR-GAT001.2

Prepared for:	GCP Applied Technologies Inc
Address:	-
Part Name:	MK6/HY
Part/Model/Ref Number:	-
Lot Number:	-
Samples Received Date:	February 22, 2024
Testing Period:	March 18 - November 15, 2024
Scope Requested:	Regulation of Certain Chemical Substances and Mixtures under Section 6 of the Toxic Substances Control Act, 40 CFR Part 751 Significant New Uses of Chemical Substances, 40 CFR Part 721, specifically LC-PFAC Reportable PFAS
Date of Report:	November 18, 2024

Results

Directive / Regulation	Substance Listing	Conclusions	Substances
TSCA (40 CFR 751)	-	Compliant	-
TSCA (40 CFR 721)	-	Compliant	-
Reportable PFAS	-	Not detected	-

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	Julie Van Moorsel	Alex Levesque	March 27, 2024
2	Added follow up result	Julie Van Moorsel	Alex Levesque	November 18, 2024

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 analyzer (Appendix A.2.1).

1.1.2 Results – Table 1

Sample		Results (ppm)			
Number	Description	Sb	Br	Cl	P
116833-1	Grey Block	<LOD	68 ± 13	1648 ± 772	<LOD

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

1.2 FTIR Spectroscopy

1.2.1 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 or melamine. Test standards are detailed in Appendix A.10.

1.2.2 Results

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

1.3 Engineering Analysis

Methodologies are described in Appendix A.4.

Sample		TSCA		Reportable PFAS	
Number	Description	Risk	Comments	Risk	Comments
116833-1	Grey Block	Low		High	Possible fluorocarbons

1.4 CIC

1.4.1 Testing

In cases where XRF or Engineering Analysis are inconclusive, CIC provides a means of identifying elements with low molecular weight. Test standards are detailed in Appendix A.6.

1.4.2 Results

Testing was carried out on the samples shown in the table below (ND = not detected).

Sample		Results (ppm)
Number	Description	F
116833-1	MK-6 HY	ND

NOTE: Testing carried out by approved external provider.

1.5 Conclusions for Substances Assessed in Follow-Up Testing

Sample		Conclusions
Number	Description	Reportable PFAS
116833-1	MK-6 HY	Not detected

2 Photographs



116830 As received



116831 As received



116832 Exploded view



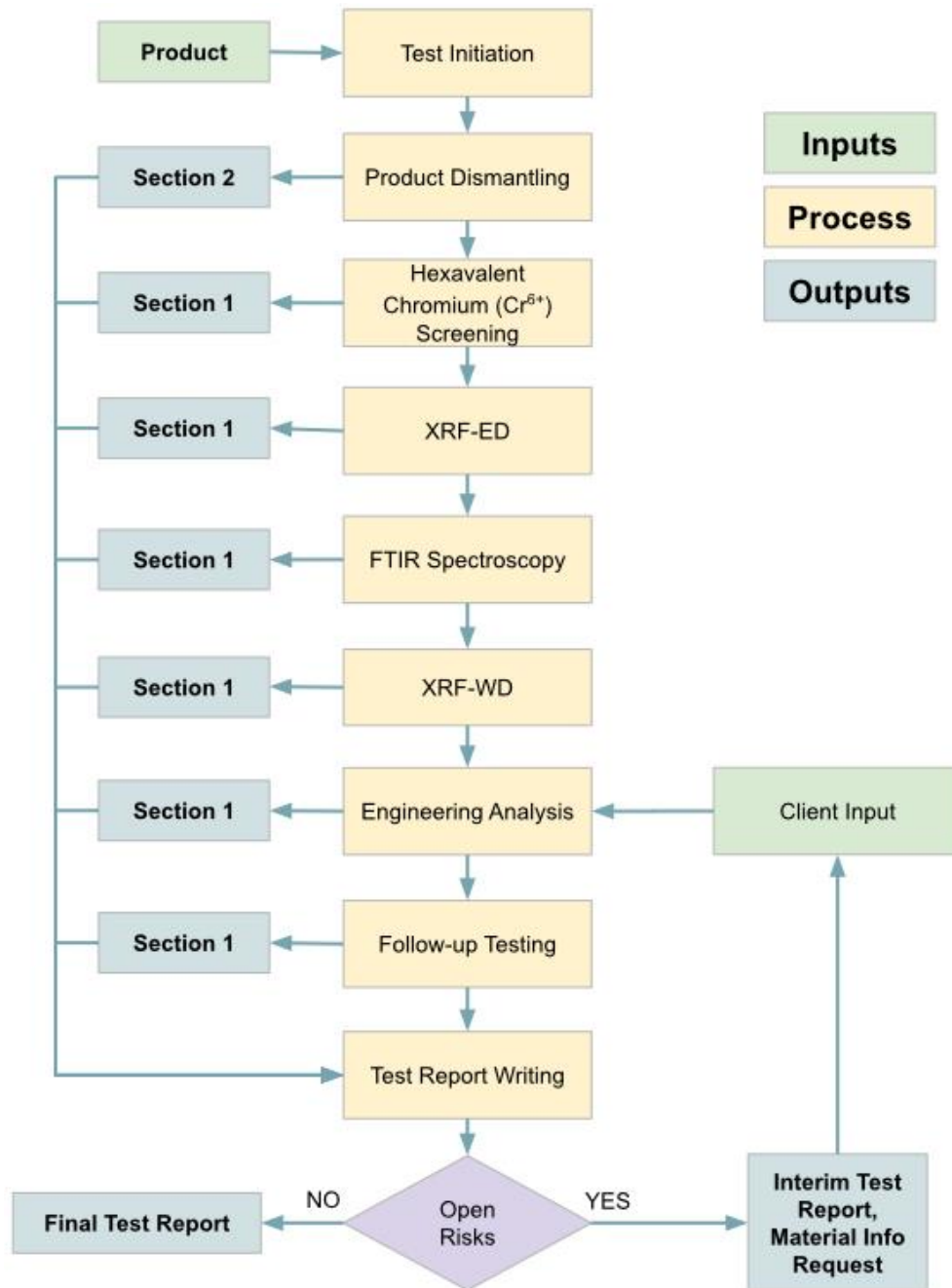
116833

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 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	PU	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
Co	-	-	-	80	1200	75	450	-	-	-
Ni	12	75	-	95	350	175	600	-	-	-
Sb	22	25	-	15	50	60	300	6	7	5-35
Br	3	8	-	5	20	25	35	1	1	N/A
Cl	1000	N/A	-	N/A	N/A	N/A	N/A	100	N/A	N/A
P	90	250	90	N/A	N/A	N/A	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 XOS (LOD of 55 ppm) for quantification.

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
F	50

Very low measurement between 50 and 99 ppm F may be listed as inconclusive until confirmed by alternative test methods (such as combustion ion chromatography) or engineering review.

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

In the case of a difference in fluoro determination between WD-XRF and FTIR, the WD-XRF will be used as the determining test. WD-XRF is far more sensitive than FTIR and has less opportunity for confusion with unique materials.

A.3 Hexavalent Chromium (Cr⁶⁺) Screening

The Claigan Chromium TNTplus process with denatured alcohol is a screening process for Cr⁶⁺. 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 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 target³. 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
SCCP's	ISO 18219: Leather – Determination of chlorinated hydrocarbons in leather (SCCP's)

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. 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.7 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.8 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.6. 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/cm²/week.

The compliance limit for EN 1811 is defined as:

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

A.9 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.10 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 $\sim 2,000$ 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, MCCPs, BPA, and orthophthalates, SCCPs, MCCPs, and BPA would generally be seen as low risk if high concentrations of orthophthalates are not expected to be present. The detailed procedure is as follows:

1. Claigan reviews peaks in ranges from $1597\text{-}1603 \text{ cm}^{-1}$ and $1577\text{-}1583 \text{ cm}^{-1}$ for possible phthalate risks. Samples with peaks identified in both ranges (double-peaked) are marked as "yes". Otherwise, the sample is marked as "no".
2. If a spectrum identifies the material as potentially being a fluorocarbon, it is indicated as having a Fluorocarbon Marker present. The result may be verified by XRF-WD and/or CIC testing.

3. 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".
4. If the FTIR is inconclusive, the result is labelled with "Inconclusive".

A.11 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 $\mu\text{g}/\text{cm}^2$. 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 $\text{K}_2\text{HPO}_4 \cdot 3\text{H}_2\text{O}$ 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 $\mu\text{g}/\text{cm}^2$ is a positive result
EN/IEC 62321-7-2	Polymers, Electronics	>0.13 $\mu\text{g}/\text{cm}^2$ is a positive result
ISO 17075-1	Leather	<3 mg/kg is compliant with REACH Article 67 restrictions

A.12 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
	Benzo[a]anthracene Benzo[b]fluoranthene Benzo[j]fluoranthene Benzo[k]fluoranthene Benzo[g,h,i]perylene Benzo[a]pyrene Benzo[e]pyrene Dibenzo[a,h]anthracene Dibenzo[a,h]pyrene Dibenzo[a,l]pyrene Chrysene Fluoranthene Fluorene Indeno[1,2,3-c,d]pyrene Naphthalene Phenanthrene Pyrene		
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-Toluyldiamine 2,4,5-Trimethylaniline o-Anisidine 4-Aminoazobenzene 2,4-Xylidine 2,6-Xylidine	None	Azocolourants
UV Stabilizers	UV320 UV327 UV328 UV350	None	UV Stabilizers
Perfluoroalkyl Carboxylates	Perfluoro-butanoic acid (PFBA) Perfluoro-pentanoic acid (PFPeA) Perfluoro-hexanoic acid (PFHxA) Perfluoro-heptanoic acid (PFHpA) Perfluoro-octanoic acid (PFOA) Perfluoro-nonanoic acid (PFNA) Perfluoro-decanoic acid (PFDA) Perfluoro-undecanoic acid (PFUnDA) Perfluoro-dodecanoic acid (PFDoA) Perfluoro-tridecanoic acid (PFTrDA)	PFOA/PFNA, LC-PFAC	P25

Family Name	Family Members	Substances Often Tested Individually	Short Form
	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-undecanoic acid (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)		
Perfluoroalkyl Carboxylates and 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) Perfluoro-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
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) 3 Tricyclohexyltin (TcyT) Monophenyltin (MphT) Tetraoctyltin (TeOT) Tetraoctyltin (TeET)	DOT/MOT	

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, Cr⁶⁺, 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
- 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>.

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.1.3 RoHS Proposed MCCP/TBBPA

Assessment of compliance for RoHS proposed restricted substances (MCCP's, TBBPA) is based on the risk-based approach of the EN/IEC 62321 standards. While under proposal these substances are provisionally restricted at 1000 ppm.

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.

In cases where D6 is found to be in concentration lower than 1000 ppm, concentrations of associated D4 and D5 are also expected to be below 1000 ppm.

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 both 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.

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.

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 $C_nF_{2n+1}-C(=O)OH$ where $n=8, 9, 10, 11, 12, \text{ or } 13$ (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.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 Claijan 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 Directive

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

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 (Cr⁶⁺) 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 licensing 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	1,000

The risk for PFOA is considered to be low if the result from XRF-WD is inconclusive.

C.11 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.12 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.13 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.14 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.15 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.16 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.17 PFAS Restrictions (P25)

Testing by LC-MS/MS to an industry standard list (P25) of perfluoroalkyl carboxylates and substances that can degrade into perfluoroalkyl carboxylates. The list includes 25 short-chain and long-chain, linear- and branched-perfluoroalkyl carboxylates, perfluorotelomer alcohols, and perfluorotelomer acrylates. Refer to Appendix B for the list of substances tested. 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.

The risk for P25 is considered to be low if the result from XRF-WD is inconclusive.

C.18 PFAS Restrictions (Extended P13)

Testing by LC-MS/MS to an industry standard list (P13) of perfluoroalkyl sulfonates. This list includes 13 short-chain and long-chain perfluoroalkyl sulfonates, perfluoro sulfonamides, and fluorotelomer sulfonates. Refer to Appendix B for the list of substances tested. These substances are the most common substances in their families. Other rarer variants may exist.

P13 Substances are reported as detected. Specific regulation of a substance (if any) will depend on the jurisdiction and product. This list is intended to be forward-looking. Individual substances may not have significant current regulation.

The risk for P13 is considered to be low if the result from XRF-WD is inconclusive.

C.19 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 XOS, *HD Mobile*¹⁰¹ 4-pager brochure rev. 102815 (2015).

³ A.B. Fialkov et al., 10th Annual Meeting of AICS, *isranalytica.org.il/Abstracts/Fialkov.DOC* (2007).