Specialty Coating Systems, Inc. response report to PFAS restriction proposal

Use of PFAS in the conformal coating of electronic components and medical devices

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Acronyms and Abbreviations

Name	Description
ACH	Air Change per Hour
ALD	Atomic Layer Deposition
AR	Acrylic Resin
ART	Advanced Reach Tool
ASTM	American Standard for Testing and Materials
BGA	Ball Grid Array
CAGR	Compound Annual Growth Rate
CVD	Chemical Vapor Deposition
[redacted]	[redacted]
[redacted]	[redacted]
EEA	European Economic Area
EEE	Electrical and Electronic Equipment
ELV	End of Life Vehicle
EPD	Extender Producer Responsibility
ESD	Electrostatic Discharge
EWC	European Waste Code
IEC	International Electronic Commission
LHV	Lower Heating Value
LOD	Limit of Detection
LOQ	Limit of Quantification
MEMS	Micro Electro-Mechanical Systems
OEMs	Original Equipment Manufacturers
OELs	Occupational Exposure Limits
OSH	Occupational Safety and Health
PCBs	Printed Circuit Boards
PDS	Parylene Deposition System
PE	Polyethylene
PFAS	Per- and Polyfluorinated Substances
PPE	Personal Protective Equipment
RF	Radio Frequency
RoHS	Restriction of Hazardous Substances in Electrical and Electronic Equipment
RRR	Reusability Recyclability and Recoverability
SCS	Specialty Coating Systems, Inc.
SDS	Safety Data Sheet
SR	Silicon Resin
[redacted]	[redacted]
UECA	United Electronics Coating Association
USP	US Pharmacopeia
UR	Urethane (Polyurethane) Resin
WEEE	Waste from Electrical and Electronic Equipment
WFD	Waste Framework Directive

CBI 1

CBI 1

1. EXECUTIVE SUMMARY

Specialty Coating Systems, Inc. (hereafter SCS) is a US company providing conformal coating service to protect a wide range of products used in various innovative solutions and applications. Conformal coatings are thin (25-250 µm), nonconductive, dielectric layers that are used to protect electronic components and medical devices from damage due to contamination, salt spray, moisture, fungus, dust and corrosion, extreme temperatures and UV exposure. While conformal coatings were first used to protect military and aerospace applications, their use has expanded over the last five decades to include medical devices, consumer electronics, transportation electronics and more.

SCS is global leader of Parylene HT® conformal coating, which is a fluorinated Paraxylylene variant. The conformal coating process consists of a chemical vapour deposition (CVD) of the Parylene HT® dimer that leads to the polymerisation of Parylene HT onto the materials or items' surfaces. SCS´s subsidiary company Galentis s.r.l. located in Italy is the producer and supplier of the Parylene HT® dimer. This ownership allows SCS complete control over their proprietary dimer, manufacturing recipes and production processes to ensure SCS Parylene HT® dimer meet the highest quality standards.

In comparison to other Parylene variants and other thin coatings, Parylene HT conformal coating offers superior solutions to many existing packaging and reliability challenges of the electronics industry because of its excellent electrical and mechanical properties, chemical inertness, biocompatibility, long-term UV stability and long-term thermal stability at high temperature exposure to over 350° C (which can rise to 450°C in the short-term for some applications). Therefore, Parylene HT conformal coating is used in a wide range of applications where functioning is required under harsh and extreme conditions.

End-use temperatures of electronics continue to increase as miniaturisation of devices occurs and power requirements increase. Parylene HT has demonstrated low dielectric constant and dissipation factor in their coatings, which are very relevant for radio-frequency (RF) electronics to preserve signal integrity and sensitivity, while also being required to operate in high humidity and corrosive environments.

As the demands of the electronics industry are increasing as regards the need for safer products, higher protection, and higher reliability of various electronic components (such as pressure and temperature sensors, Printed Circuit Boards (PCB) Micro Electro-Mechanical Systems (MEMS) optoelectronic devices, fuel cell components and nanoelectronic parts, etc.), Parylene HT has been demonstrated to be the only suitable thin organic coating that can provide much-needed protection for high-tech sophisticated parts against extreme conditions such as UV exposure and to be thermally stable at higher temperatures.

SCS acknowledges the need to minimise the risk that the uses of Per- and Polyfluorinated Substances (PFAS) may present to the environment and humans. Although Parylene HT was not previously considered a PFAS, Parylene HT would now fall within the scope of the definition of a PFAS substance as described in the restriction proposal. Consequently, SCS has elaborated this report to present relevant data on the uses and applications of Parylene HT conformal coating processes and their efforts to find technically suitable alternatives. The information provided demonstrates the necessity of the use of Parylene HT conformal coating, the control of potential emissions to the environment, the potential for substitution, and the importance the continued use Parylene HT conformal coating in the European Economic Area (EEA).

The conclusions from this study are that:

1. **There are currently no PFAS-free alternatives to Parylene HT conformal coating that can ensure that electronics components can remain operative under harsh conditions such as UV exposure and can remain thermally stable at higher temperatures.**

None of the potential alternative materials and technologies evaluated by SCS are currently suitable to substitute Parylene HT in the conformal coating of electronics uses in applications in industry sectors such as electronics, automotive, aerospace & defence and some medical applications. While some of the PFAS-free alternatives can offer corrosion protection (e.g., plasma coating), mechanical flexibility (resin coating), dielectric strength (acrylic resin), there is no alternative that meets all requirements, including thermal and UV stability, mechanical flexibility and that can therefore be used in the many applications as they require the combination of these properties.

A PFAS-free alternative in conformal coatings would require extensive research and testing before their technical feasibility can be assessed, as they are primarily used on applications that do not require both UV and thermal resistance or other combined feasibility criteria.

2. SCS and Galentis can ensure that any potential PFAS emissions are fully controlled in their manufacturing operations

SCS has locations across the globe. Headquartered in Indianapolis, SCS has nine coating centers in North America, seven coating centers in Asia and five coating centers in Europe: the UK (non-EEA), Ireland, Czech Republic, Germany, and Switzerland (non-EEA). All five sites in Europe are multi-purpose coating centers and ISO 9001 certified facilities.

The production process of Parylene HT® dimer is subject to a rigorous containment, which is achieved by the technical design of the process and the equipment aimed at preventing the releases for workers and environment. The efficiency of the containment measures for Parylene HT® dimer are further confirmed by mass balance data and by occupational and environmental analytical monitoring. All solid and liquid wastes generated during production that are contaminated with Parylene HT® dimer are collected and disposed of by means of incineration.

The coating process employing the Parylene HT® dimer is a closed process where all the Parylene HT dimer is consumed, with no or extremely low potential for exposure to workers and environment.

3. SCS request for a specific time limited derogation for the use of Parylene HT® dimer in the conformal coating process

As there are no suitable alternatives for the applications where Parylene HT is used in, and the time needed for developing a suitable alternative could take more than ten years, SCS would like to request the consideration of the following specific derogation**:**

Derogation for the use of Parylene HT® dimer (CAS 3345-29-7) in the process of conformal coating in applications for electronics and medical devices when operative performance is required to be maintained at a wide range of extreme temperatures (-40°C to higher than 350°C) and/or with long-term UV exposure.

SCS believes that the absence of a derogation to allow the continued and limited use of Parylene HT® dimer in the conformal coating would result in the following societal impacts:

- A reduction of reliability and durability of the electronic components and systems, that will also compromise: i) the performances of final EEE (Electrical and Electronic Equipment); ii) the performances and the safety of the vehicles and of defense instruments and assemblies, iii) and medical devices placed on the market in the EEA, whose systems might be subject to early failure. Likewise, there will be an inability to service and repair existing products;
- Likewise, a reduction of the quality and standard of health services, since more invasive surgeries and medical devices might be required as an alternative, with the increasing risk of cross infection for patients.

2. BACKGROUND INFORMATION

2.1 Regulatory background on PFAS: the EU proposed restriction

On 22 March 2023, ECHA officially published the universal PFAS restriction proposal, and initiated a six-month public consultation. The restriction proposal includes a number of proposed time-limited derogations and derogations for reconsideration for some of the assessed (sub-)uses. The decisions on derogations were made on the basis of the availability of alternatives and the feasibility of substitution, along the potential for environmental emissions for each (sub-)use.

The public consultation requests stakeholders to provide any relevant information to the uses, alternatives, waste management and environmental fate of PFAS in the EEA.

The requested information is on:

1. Sectors and (sub-)uses.
2. Emissions in the end-of-life phase (in the EEA), including emission levels and waste treatment methods.
3. More specifically, the effectiveness of incineration with respect to the destruction of PFAS
4. Impacts on the recycling industry with respect to the concentration limits for PFAS and any incurred costs.
5. Tonnage and emissions for the proposed derogations.
6. Alternatives and socioeconomic impacts for uses not assessed in the restriction proposal, including volumes, functionalities of PFAS, suitability and availability of alternatives, costs, time and difficulties for substitution, and any socioeconomic impacts in case substitution is not feasible.
7. Any information on alternatives and socioeconomic impacts to justify the derogations that are marked for reconsideration by the dossier submitters.
8. Any additional information on alternatives and socioeconomic impacts for identified uses that have no proposed derogations in the restriction proposal.
9. The degradation potential of specific PFAS sub-groups.

2.2 Information on the stakeholder

Specialty Coating Systems, Inc. (hereafter SCS), is a US company providing conformal coating service to protect a wide range of innovative solutions and applications. With over 50 years of experience in conformal coating engineering and applications, SCS is the world leader in Parylene, liquid, plasma polymerized, atomic layer deposition (ALD) and multilayer conformal coating technologies. SCS is a direct descendant of the companies that originally developed Parylene. Since 2016, SCS is a KISCO company.

Conformal coatings are generally thin, nonconductive, dielectric layers that are used to protect devices and components from damage due to contamination, salt spray, moisture, fungus, dust and corrosion. While conformal coatings were first used to protect military and aerospace applications, their use has expanded over the last five decades to include medical devices, consumer electronics, transportation electronics and more. In recent years, the development of new materials and coating processes has enabled an even larger variety of items to be coated in production facilities around the world.

SCS is one of the few Parylene suppliers around the world that own the manufacturing capabilities for the Parylene dimers used in the conformal coating process throughout SCS´s subsidiary company Galentis s.r.l. (hereafter Galentis) located in Italy. This ownership allows SCS to own complete control over their proprietary dimer variants, manufacturing recipes and production processes to ensure SCS dimers meet the highest quality standards.

Galentis stands as an industry leader in the manufacture of high-quality fine chemicals, specialty fine chemicals, polymers for medical devices, intermediates for non-active and active pharmaceutical ingredients, and other key intermediates for the synthesis of pharmaceuticals. Galentis is subjected to the direction and coordination of Specialty Coating Systems, Inc.

Galentis produces GALXYL®, a series of Parylene dimers that are used as raw material for the Parylene conformal coating process. The unique nature of the material's deposition enables the resultant Parylene coatings to reliably protect, preserve and insulate a wide variety of substrates.

SCS has locations across the globe. With a headquarters in Indianapolis, SCS has nine coating centers in North America, seven coating centers in Asia and five coating centers in Europe: the UK (non-EEA), Ireland, Czech Republic, Germany, and Switzerland. All five sites in Europe are multi-purpose coating centers and ISO 9001 certified facilities.

SCS belongs to the United Electronics Coating Association (UECA)[1]. The UECA represents the leading companies providing protective coatings for the electronics industry that are used throughout the world economies. One of UECA's key objectives is to support the electronics industry to deliver a sustainable future, enabling electronics re-cycling and reparability, significantly reducing e-waste, eliminating environmentally hazardous materials and facilitating the circular economy.

2.3 Aim and scope of the report

SCS intends to submit this report to the public consultation on the proposal for a restriction of PFAS, which was initiated by ECHA and runs until 25 September 2023. As part of their response, SCS wants to present relevant data on the uses / applications of PFAS in their conformal coating processes, which are applied in a number of products in industry sectors and applications such as electronics, medical devices, automotive, and aerospace and defence. The information provided will demonstrate the necessity of the use of PFAS in these applications, the potential for substitution, and the importance of the use, and continued use, in the EEA.

The PFAS restriction proposal does not propose a specific derogation for use of PFAS on conformal coating processes and more specifically in electrical and electronic components and medical devices, which is where PFAS- based conformal coating processes are used in.

It should also be noted that the use of PFAS-based conformal coating in medical devices applications may fit within certain sub-sectors and fall under some of the proposed limited derogations. However, the envisioned potential substitution timeline may be much longer than 12 years.

The aim of the report is to substantiate the case for a targeted or broader derogation for uses of PFAS in the conformal coating process in components which form a critical part of electronic equipment, medical equipment and devices, automotive electronics, and aerospace and defence equipment.

The information provided in this report primarily relates to following points of the specific requests for information in the public consultation, as summarised in Section 2.1 of this document.

1. Sectors and (sub-)uses.
2. Emissions in the end-of-life phase (in the EEA), including emission levels and waste treatment methods.
6. Alternatives and socioeconomic impacts for uses not assessed in the restriction proposal, including volumes, functionalities of PFAS, suitability and availability of alternatives, costs, time and difficulties for substitution, and any socioeconomic impacts in case substitution is not feasible.

[1] Home - United Electronics Coatings Association (theueca.org)

7. Any information on alternatives and socioeconomic impacts to justify the derogations that are marked for reconsideration by the dossier submitters.
8. Any additional information on alternatives and socioeconomic impacts for identified uses that have no proposed derogations in the restriction proposal.

This report focuses on the use of the fluorinated Parylene HT® dimer in conformal coating process, which leads to formation of Parylene HT polymeric in applications such as electronics, medical devices, automotive and aerospace and defence.

The production of Parylene HT® dimer takes place at Galentis (a SCS company) in Italy and the material is supplied to several facilities of SCS located both in the EEA and outside the EEA, where the dimer is used in the conformal coating process. The final products containing PFAS (Parylene HT polymer) are directly commercialised or imported in the EEA. Therefore, the discussion on socioeconomic impacts from a no-derogation scenario will focus only on the EEA.

3. BASELINE SCENARIO

3.1 Description of use(s)

3.1.1 Conformal coating process

Conformal coating is a protective coating of thin polymeric film applied mainly to printed circuit boards (PCB). The coating is named conformal since it conforms to the contours of the PCB or other surfaces where it is applied to. Conformal coatings are typically applied at thicknesses of 25-250 µm to the electronic circuitry and provide protection against moisture, dust, chemicals and temperature extremities. Likewise, SCS offers a variety of advanced and traditional coatings for the medical sector, particularly for applications requiring biocompatibility.

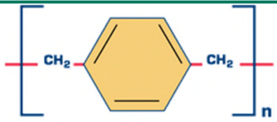
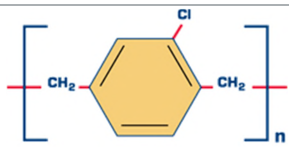
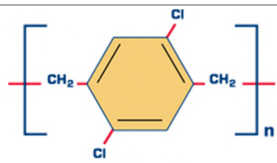
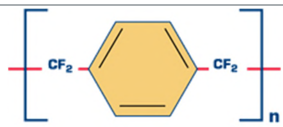
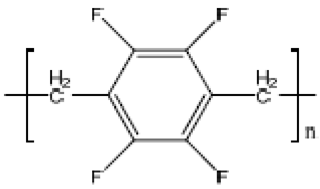
Conformal coating can be applied in several ways, including brushing, spraying, dispensing, dip coating and vapour deposition process. A number of materials can be used as a conformal coating such as acrylics, silicones, urethanes and Parylene. Each has their own characteristics, making them preferred for certain environments and manufacturing scenarios. Most circuit board assembly firms coat assemblies with a layer of transparent conformal coating, which is lighter and easier to inspect than potting.

SCS is a global leader in Parylene-based conformal coating. Parylene is the name for a series of polymers obtained from Paraxylylene, which are considered as very effective conformal coatings. Parylene coatings have the unique characteristic that they are deposited at room temperature through a vapour deposition process. Parylenes are chemically stable and provide excellent moisture, chemical and dielectric barrier properties. Parylene coatings also offer superior thermal stability and UV stability, dry-film lubricity, notable mechanical properties and high tensile strengths. These properties make SCS Parylene coatings suitable for a number of applications throughout the medical device, electronics, transportation, defence and aerospace industries.

SCS is able to offer conformal coating with a wide range of Parylene variants, which may be selected depending on the properties they can provide (Table 3-1). These members (or variations of Parylene) each offer their own, slightly different, coating properties to engineers. Commercially available Parylene variants, along with their respective properties, include[2]:

[2] SCS website – SCS Parylene properties. Available online at: https://scscoatings.com/parylene-coatings/parylene-properties/, accessed on 19 June 2023

Table 3-1 Parylene Variants, their properties and chemical structures

Parylene variant	Chemical structure
Parylene N is poly(para-xylylene), a completely linear, highly crystalline material. Parylene N is a primary dielectric, exhibiting a very low dissipation factor, high dielectric strength, and a low dielectric constant invariant with frequency.	 *Parylene N*
Parylene C is produced from the same raw material (dimer) as Parylene N, modified only by the substitution of a chlorine atom for one of the aromatic hydrogens. Parylene C has a useful combination of electrical and physical properties, plus a very low permeability to moisture and corrosive gases.	 *Parylene C*
Parylene D is produced from the same raw material as Parylene N, modified by the substitution of chlorine atoms for two of the aromatic hydrogens. Parylene D is similar in properties to Parylene C with the added ability to withstand slightly higher use temperatures.	 *Parylene D*
Parylene HT® replaces the alpha hydrogen atom of the N dimer with fluorine. This variant of Parylene is useful in high temperature applications (short term up to 450°C) and those in which long-term UV stability is required. Parylene HT® also has the lowest coefficient of friction and dielectric constant, and the highest penetrating ability of the Parylenes.	 *Parylene HT®*
ParyFree®, the newest and a unique member of the series, replaces one or more hydrogen atoms of the Parylene N dimer with non-halogenated substituents. This halogen-free variant offers the advanced barrier properties of Parylene C and adds improved mechanical and electrical properties compared to other commercially-available Parylenes. ParyFree® optimizes the critical combination of barrier, electrical and mechanical properties to provide robust protection against moisture, water, corrosive solvents and gases, while complying with halogen-free requirements of select industries worldwide.	Trade Secret
Parylene F/VT-4 replaces the aromatic hydrogen atom of the N dimer with fluorine. This variant of Parylene is useful in higher temperature applications (short term up to 200°C but degrades rapidly as temperature increases). The film offers barrier, electrical and mechanical properties similar to other Parylene variants. Parylene F is not UV stable.	 Parylene F

Amongst the different Parylene variants Parylene HT stands out for performing in applications that need to operate at extreme temperatures (short term up to 450°C) and those in which long-term UV stability is required. In comparison with other Parylene variants- based coating, Parylene HT diplays the lowest coefficient of friction and dielectric constant, and the highest penetrating ability of the Parylenes.

3.1.2 Fields of application of Parylene HT® conformal coating

Parylene HT offers solutions to many existing packaging and reliability issues of the electronics industry in part because of its excellent electrical and mechanical properties, chemical inertness, and long-term thermal stability at high temperature exposure to over 350° C (which can rise to 450°C in the short-term for some applications)[3].

Parylene HT based conformal coating is used in a wide range of application fields such as:

- Electronics
- Automotive / Transport
- Aerospace and defence
- Medical devices

3.1.2.1 Electronics

Parylene HT polymer ensures complete coating of circuit boards, ferrite cores and other electronics packages such as Micro Electro Mechanical Systems (MEMS), lab-on-a-chip technologies and sensors. Parylene HT conformal coatings play a critical role in protecting electronic components.

As electronic packages tendency to become smaller and more complex, SCS can deliver ultra-thin electronic coatings that meet industry needs. Although the different Parylene variants can offer similar desired properties, Parylene HT based conformal coating excels by deploying the ability to meet the growing requirements of higher dielectric capabilities, higher temperature integrity and mechanical processing of the dynamic electronic industry. In addition, Parylene HT polymer coating accurately conforms to the parts due to its molecular level deposition characteristics. Parylene HTs suitability and biocompatibility allow its use in sensors and in active electronic devices for various industries, in particular in medical devices, which include enhancing high temperature applications and technologies.

Parylene HT provides an advanced protective coating that can enhance product reliability without hermeticity under many high temperature operating applications. Parylene HT is well suited for electrical and environmental protection of various micro and nano electrical components, biosensors, PCB and other electronic components. Parylene HT is also suitable for contamination and corrosion control, dry lubrication and protection of high density and high-speed integrated circuits.

For examples of electronics applications that require Parylene HT conformal coating to ensure trouble-free operation refer to Table 3-2.

3.1.2.2 Automotive / Transport

The transport industry has long relied on conformal coatings to help protect critical electrical systems and components. Industry-leading products such as SCS Parylene HT, which is capable of withstanding temperatures up to 450ºC, help serve the needs of Original Equipment Manufacturers (OEM), Tier 1 and Tier 2 manufacturers in this evolving market. Automotive operating environments often range from -40°C to higher than 350°C. In addition, many applications also experience prolonged exposure to UV light. Parylene HT offers measurable UV stability after more than 2,000 hours of UV exposure (ASTM G154).

[3] Rakesh Kumar, F. Ke, A. Summers, L. Young. (2016). A high temperature vapor phase conformal coating for improving reliability of harsh environment electronics. 39th International Spring Seminar on Electronics Technology (ISSE). DOI:10.1109/ISSE.2016.7563174

In general, SCS Parylene-based conformal coatings provide excellent moisture barrier, chemical barrier and electrical isolation properties that protect automotive components against corrosive liquids, fluids, gases and chemicals, even at elevated temperatures. While several conformal coating variants offer similar properties, none provide all the properties that Parylene HT offers. Parylene HT stands out for the specific protection it offers the automotive industry.

With the accelerated development of electric, hybrid and fuel cell technologies, Parylene conformal coating have been demonstrated to offer exceptional dielectric properties, ensuring that the high level of power required for operating these electronic systems will not be weakened or distorted. Power inverters often rely on conformal coatings for their moisture barrier and electrical isolation properties. Additionally, conformal coatings are being increasingly used by electric vehicle charging station manufacturers due to harsh outdoor conditions that impact the functionality of these stations and vehicle charging connectors. Fuel cells operate in the midst of corrosive compounds at elevated temperatures, a very harsh environment for electronics. A selection of conformal coatings, including Parylene HT is chemically structured to provide the level of protection that these components require.

For examples of automotive applications that require Parylene HT conformal coating to ensure trouble-free operation refer to Table 3-2.

3.1.2.3 Aerospace & Defence

SCS's lightweight coating solutions are used in weight-sensitive components in aircraft, space probes and uncrewed aerial vehicles (UAVs). Conformal coatings are often relied on to protect electronics and components from moisture, fumes and dust in the harshest environments, chemical and biological agents, and subsequent decontamination processes. Applications of conformal coating in the aerospace and defence comprises of electronic devices within defense aircraft, missile and ground systems to components that must operate in the depths of space, ensuring long and trouble-free life.

Aerospace and defence applications are exposed to a wide range of temperatures. Parylene HT coatings provide thermal stability to ensure functioning of components within these harsh operating environments that span from the cryogenic levels of space (-150°C to -273°C) to extreme temperatures of 450°C.

For examples of aerospace and defence applications that require Parylene HT conformal coating to ensure trouble-free operation refer to Table 3-2.

3.1.2.4 Medical devices

SCS has applied their medical coating experience and technologies to support a range of medical device applications from elastomeric seals and forming mandrels to electrosurgical devices instruments, infusion devices and long-term implants such as stents. SCS offers biocompatible and biostable Parylene coating solutions for medical devices and components to ensure excellent moisture, chemical and dielectric barrier protection.

Parylene HT offers additional low coefficient of friction where lubricity is important. In addition, it provides superior performance when compared to other Parylene to protect the Human body from electronic impulses and other functional inevitabilities – vibrations, etc. – that are required from efficient operation, while safeguarding the device itself from often harsh bodily fluids. Likewise, its pinhole-free coverage prevents internal leakage into, or incursion from, the bodily environment. Parylene HT is exceptionally stable biologically, chemically and electronically, which provides an effective electrical insulator that will not degrade in the presence of electrical current. It resists solvents and is insoluble at temperatures to 150°C. These factors generate reliable consumer safety under most performance circumstances, for the majority of Parylene's uses. Parylene HT is also the preferred choice for medical electronics. For examples of medical applications that require Parylene HT conformal coating to ensure trouble-free operation refer to Table 3-2.

3.1.2.5 Summary of applications

Table 3-2 lists Parylene HT coating applications in key industries where the coating offers a superior and critical advantage in comparison to other coatings. Description of the properties required for applications are also given. Applications or products that are commercialised in the EU market have been also listed, highlighting the reasons for using Parylene HT conformal coating to ensure their functioning performance.

Table 3-2 Parylene HT coating applications in key industries

Industry / market sector	Description of the properties required for applications	Applications / products (EEA market)	Functionality of Parylene HT conformal coating
Electronics and semiconductors	■ Inert barrier protects against moisture, chemicals, salts, solvents ■ Exceptional UV stability ■ Thermal stability – up to 350°C long-term, 450°C short-term ■ Optical clarity and uniform, ultra-thin nature ensure signal transmission is never lost or distorted ■ Low dielectric constant and dissipation factor ■ Advanced adhesion technologies ensure coating properties of remain intact	[redacted] CBI 2	Chemical resistance & Thermal stability UV stability Thermal stability & moisture barrier Thermal stability Thermal stability Thermal stability
Automotive / Transportation	■ Ultra-thin and lightweight ■ Moisture, chemical and solvent barriers ■ Low dielectric constant and dissipation factor ■ Superior thermal stability (-40° C to 350° C) ■ UV stability ■ Excellent crevice and multi-layer penetration ■ Thin films add minimal mass to delicate components	[redacted] CBI 2	Thermal stability Thermal stability Thermal stability
Aerospace & Defence	■ Ultra-thin and conformal ■ Moisture and chemical barrier ■ Low dielectric constant and dissipation factor ■ Thermal stability and UV stability ■ Excellent crevice and multi-layer penetration ■ Ultra-thin films add minimal mass to delicate components	[redacted] CBI 2	Chemical resistance, UV & Thermal stability Thermal stability & Dielectric properties Chemical resistance, UV & Thermal stability Thermal stability Thermal stability Thermal stability Thermal stability Thermal stability Thermal stability Thermal stability Thermal stability

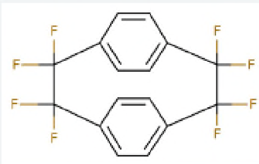
Industry / market sector	Description of the properties required for applications	Applications / products (EEA market)	Functionality of Parylene HT conformal coating
			Thermal stability UV stability
Medical devices	■ Biocompatibility and biostability ■ Excellent moisture and chemical barrier and antimicrobial properties ■ Excellent dielectric properties ■ Excellent crevice and multi-layer penetration ■ Ultra-thin films add minimal mass to delicate components ■ Surgical jaws for cutting and cauterizing, coating used for electrical isolation. ■ Used as a release agent in moulds	[redacted] CBI 2	Low dielectric constant & dissipation factor Biocompatibility, crevice penetration Thermal stability UV stability

3.2 PFAS substance(s) in use and volumes of use

Parylene HT® dimer

Parylene HT® dimer is a fluorinated variant of Parylene N, with the eight hydrogen atoms on the aliphatic chain replaced by fluorine atoms. The Parylene HT® dimer is a crystalline solid and is used in the subsequent conformal coating operations.

Galentis (a SCS company) produces the dimer at their plant in Marcon, Italy and has registered Parylene HT® dimer under REACH, in the tonnage band of 1-10 t/year. The Figure 3-1 shows substance identification details as extracted from the ECHA Registered Dossier webpage[4].



Display Name:	2,2,3,3,8,8,9,9-octafluorotricyclo[8.2.2.$2^{4,7}$]hexadeca-1(12),4,6,10,13,15-hexaene
EC Number:	639-791-8
CAS Number:	3345-29-7
Molecular formula:	C16H8F8
IUPAC Name:	2,2,3,3,8,8,9,9-octafluorotricyclo[8.2.2.$2^{4,7}$]hexadeca-1(12),4,6,10,13,15-hexaene

Figure 3-1 Parylene HT® dimer REACH dossier substance identification.
(Taken from ECHA website)

Parylene HT® polymer

The conformal coating of Parylene HT® dimer carried out at the SCS sites in the EEA consists of a chemical vapour deposition (CVD) of the Parylene HT® dimer that leads to the polymerisation of Parylene HT onto the materials or items' surfaces.

It must be noted that the content of the Parylene HT polymeric film on the articles is very low. SCS conformal coats ca. 1 million units a year using the Parylene HT® dimer, which is converted to its polymeric form via the CVD process. As the fluoropolymer coated resulting films is typically <30 microns thick, it is essentially massless in the coated item or component, which represent less than 1 ton of Parylene HT® dimer of use per year.

It should be noted that the use of the Parylene HT® dimer for the coating process takes place in the EEA and coated articles can be either used inside or outside the EEA. The actual share of those coated articles eventually sold in the EU is not known to SCS.

In addition, as SCS's customers depend on these components to be Parylene HT conformal coated for the successful functioning of their electronic and medical devices, SCS wishes to highlight the importance of the use and the difficulty to identify alternatives for such demanding applications. This is a main concern for electronic equipment manufacturers, as for these applications the coating needs to display sufficient protective features in a wide range of harsh conditions (temperature, UV resistance, chemical agents, mechanical stress) as well as to provide excellent moisture, chemical and dielectric barrier properties, dry-film lubricity, and biostability and biocompatibility.

[4] https://echa.europa.eu/it/registration-dossier/-/registered-dossier/34346

3.3 Market overview

3.3.1 Supply chain

The supply chain of SCS, which is relevant to the Parylene HT conformal coating services, is as below:

- Galentis s.r.l. (a SCS company) produces Parylene HT® dimer in Italy and supplies it to the coating facilities of SCS located worldwide. This means the dimer is produced in the EEA.
- SCS receives service orders to perform Parylene HT-based conformal coating from customers worldwide. Depending on the logistic and proximity, the conformal coating of SCS´s customers articles may be carried out either in coating centers located in the EEA or outside the EEA.
- Customers receive coated articles and components and can further resolve their destination to finalise and commercialise finished products.
- Final devices (containing the very small concentrations of Parylene HT polymer) will eventually be sold in the EEA and the rest of the world. The actual share of those coated articles eventually sold in the EU is not known to SCS.

3.3.2 Sales of Parylene HT conformal coating services by SCS

Table 3-3 shows the sales as of 2022 of SCS and Galentis as well as market share in the EEA and estimated future trends of Parylene HT conformal coating. SCS expect an increase demand for the Parylene HT conformal coating in the range of 20% per year.

Table 3-3 Sales revenues and market share in the EEA

Sold item	Volumes sold (mass/year or units)	Value of sales (in €)	Estimated market share in EEA (%)	Estimated future trends
Parylene HT® dimer	[redacted]	[redacted]	[redacted]	ca. 20% increase per year
Parylene HT coating services	[redacted]	[redacted]	[redacted]	ca. 20% increase per year

CBI 2

Galentis supplies all Parylene HT® dimer used by SCS. SCS have two unique use agreements in place in the EU to allow the dimer to be used in R&D environments to develop new products.

3.3.3 Market trends

The global Parylene conformal coating market is anticipated to grow at a considerable rate between 2022 and 2030. In 2021, the market grew at a steady rate and with the rising adoption of strategies by key players, the market is expected to grow over the projected time horizon[5]. Likewise, the global Parylene conformal coating market size is projected to reach 500 million USD by 2027.

According to Grand View Research report[6] the overall global conformal coatings market size was valued at USD 930.89 million in 2021 and is expected to expand at a compound annual growth rate (CAGR) of 5.9% from 2022 to 2030. The growth of conformal coatings depends on their use in various automotive, medical, consumer electronics, and aerospace and defence applications. With the increasing need for miniaturised circuitry and electronic devices, conformal coatings demand has observed a rise in the modern PCB-related applications.

In 2017, Europe accounted for 23% of the total volume share, on account of high product demand from various end-use industries including automotive and transportation, electrical and electronics,

[5] 2030 | Parylene Conformal Coating Market Research - MarketWatch
[6] Conformal Coatings Market Size Report, 2022-2030 (grandviewresearch.com)

and medical among others across major countries including Germany, France, Italy, Spain U.K., Russia and Poland.

Some of the largest manufacturers of Parylene conformal coating market worldwide are:

- Kisco (Parent company of SCS, Parylene dimers and coating service supplier)
- Galentis SRL (Parylene dimers supplier)
- Para Tech (Curtiss-Wright)
- Stratamet Thin Film
- Chireach Group
- Penta Technology
- Huasheng Group

According to Dataintelo report[7], the main growth factors accelerating the expansion of the Parylene conformal coating use can be summarised as below.

- Increasing demand for Parylene coatings in medical devices and implants owing to its biocompatibility and non-toxicity properties;
- Ascending demand for Parylene coatings from the semiconductor industry due to its superior electrical insulation properties;
- The growing use of Parylene coatings in aerospace and defense applications is due to their thinness and excellent thermal, mechanical, and chemical resistance properties.
- Increasing adoption of Parylene coatings in automotive applications due to their ability to protect components from wear and tear, corrosion, and abrasion damage.

3.4 Control of Emissions and description of risk management measures

3.4.1 Parylene HT® dimer production process

Galentis is involved in the production of different Parylene dimers, including the fluorinated Parylene HT® dimer. Galentis produces the Parylene HT® dimer at their manufacturing site in Marcon, Italy.

Galentis supplies the Parylene HT® dimer to the SCS coating centers located in the EEA (European Economic Area) and outside the EEA, where the conformal coating activities are carried out. Galentis operations are coordinated with SCS, who are the sole users of their Parylene dimers.

The sections below describe the manufacturing process of the Parylene HT® dimer and the organizational and technical risk management measures in place at Galentis sites to prevent and minimize the exposure to workers, general population and the environment.

3.4.1.1 Process description

The manufacturing process of Parylene HT® dimer can be outlined with the following steps:

1. **Loading of raw materials**: the reagents mainly consist of [redacted]. The loading of the reagents in the reactors follows a specific procedure which includes both automatic and manual processes. [redacted] is introduced in the process by an automatic system and reacts completely. Galentis has registered [redacted] as an isolated intermediate under REACH under Strictly Controlled Conditions, which have been verified by the Italian Competent Authority. The remaining reagents are introduced in the process manually. CBI 1

7 Parylene Coating Market Report | Global Forecast From 2022 To 2030 (dataintelo.com)

2. **Production**: the production process of Parylene HT® dimer involves both automatic and manual operations that are carried out under closed and semi-closed conditions. These steps include the mixing, the chemical reactions, and the physical processes (cooling, centrifugation, distillation, dilution, dissolution, and filtration). The process ends with the production of the solid Parylene HT® dimer as a powder. The Parylene HT® dimer is then manually introduced in dryers to obtain the final Parylene HT® dimer, as a solid dry powder;
3. **Packaging**: the Parylene HT® dimer is manually sealed in specific containers that prevent any possible release of the substance. The packaging consists of two sealed layers of polythene, which is further embedded in a cardboard box. The boxes are then stored in a specific room waiting for the final marketing;
4. **Sampling and Analysis**: throughout the whole process, the sampling and analysis of Parylene HT® dimer is required both for quality and for Health Safety Environment purposes.

Exhaust air and liquid/solid hazardous wastes deriving from the intermediate reactions that may be contaminated with Parylene HT® dimer are properly managed to prevent and minimise worker exposure and environmental emissions. The sections below provide the details of the risk management measures.

3.4.1.2 Risk management measures

In general, chemical exposure of workers and emissions to the environment are prevented, assessed, and managed by means of organisational and risk management measures, as required by Regional, National, and European regulations related to OSH (Occupational Safety and Health), Environmental, Product Stewardship and Quality, and by internal policies.

Organizational risk management measures

For Galentis standard procedure, all personnel are required to be trained to follow the operating instructions provided for carrying out all activities, as required by the internal procedure relating to staff education/training, in order to carry out the activities for which they are responsible. The operating instructions include process manufacturing sheets, cleaning instructions sheets, analytical methods, sampling methods, etc.

<u>Health, Safety and Environment</u>

To meet the OSH regulatory and internal policy requirements, Galentis has implemented a health and safety management system aimed to protect workers and customers present in the plant. The implementation of this system was preceded by an initial safety analysis and an accurate risk analysis and assessment, performed according to the National OSH regulation, which describe the workplaces, the activities carried out, the dangers and risks, and the prevention and protection measures adopted.

The health and safety management system is documented by the Health and Safety Management Manual and by the Safety Procedures referred to in the manual.

The manual has been structured in accordance with the following regulatory requirements:

- Legislative Decree 81/2008 “Implementation of article 1 of the law of 3 August 2007, n. 123, regarding the protection of health and safety in the workplace".
- Legislative Decree no. 109/2008 “Supplementary and corrective provisions of Legislative Decree April 9th 2008, no. 81, concerning the protection of health and safety in the workplace”.
- OHSAS 18001 standard "Management systems for the protection of health and safety in the workplace".

On a voluntary base, Galentis has adopted an Organisation, Management and Control Model, pursuant to Legislative Decree 231/2001, another control system that the company has adopted in order to comply with the aforementioned Decree.

With regard to the environmental aspects, Galentis has implemented specific operating procedures that apply for the protection of the environment, in accordance with the relevant Regional, National and European legislation.

The procedures have been structured in accordance with the following regulatory requirement:

- Legislative Decree 152/06 "Environmental code"

It should be noted that solid and liquid waste that might be potentially contaminated by Parylene HT® dimer are sent for incineration to authorised companies. With specific regard to the liquid waste, the Veneto region decree 45/2019 request the company receiving the liquid wastes from Galentis to assess both the Fluorine, the Parylene content and the Lower Heating Value (LHV) to evaluate the efficiency of the abatement technology.

According to the REACH requirements, the Parylene HT® dimer has been registered (1-10 t/year) and the SDS (Safety Data Sheet) is produced.

System maintenance and cleaning operations

The maintenance operations of the equipment used in production can be divided into routine and contingency:

- Routine maintenance includes all the interventions carried out to prevent malfunctioning and maintain normal operations, to guarantee the safety of the environment, and personnel and product quality.
- Contingency maintenance includes all the interventions carried out in order to restore full operations, after breakdowns or other technical problems.

Inspection, control and calibration interventions are scheduled annually and include the inspection of equipment, machinery, pipes and line material, which contain toxic gases or flammable solvents and the calibration of critical instruments for safety or the quality of the product. All maintenance interventions can be carried out both by internal personnel and by qualified external personnel, depending on the type of instrumentation, machine or system to be controlled. Depending on the type of maintenance intervention, a specific procedure applies.

Technical risk management measures

Workers

All workers involved in the production process of Parylene HT® dimer are instructed and trained about the hazardous properties of the final product, and the SDS relating to the materials used in the process, the use of personal protective equipment and the relative work sheet, which describes all the operations to follow.

The plant is equipped with a general air ventilation system (Air Change per Hour (ACH): [redacted] m^3/h). For the Parylene HT® dimer, where it is not possible to operate in a full closed system, a localised aspiration system is applied. Any reaction fumes captured from the general and local ventilation, are neutralized by means of a column abatement system with an alkaline recycling solution.

CBI 1

According to the occupational risk assessment, during the different steps of the production process the workers are equipped with the appropriate Personal Protection Equipment (PPE):

- Tyvek® overalls/coats: UNI EN ISO 13982 Protective clothing for use against solid particles - (type 5 clothing) + UNI EN 13034 Protective clothing against liquid chemical agents (type 6 equipment).
- Nitrile gloves (disposable): UNI EN 374-1/2 Protective gloves against dangerous chemicals and microorganisms + UNI EN 455-1/2 Disposable medical gloves.
- Rubber gloves: UNI EN 374-2 Protective gloves against dangerous chemicals and microorganisms.

- Filtering Facial Mask: UNI EN 149 Respiratory protective devices - Dust filtering half masks.
- Half Mask or Full-Face Mask matched with filters: UNI EN 140 Respiratory protective devices - Half masks and quarter masks; UNI EN 136 Respiratory protective devices. full face masks; UNI EN 14387 Respiratory protective devices - Gas filters and combined filters.
- Safety goggles: UNI EN 166 Personal eye protection.

According to the OSH legislation, an occupational monitoring scheme is in place.

The most recent occupational monitoring related to [redacted] confirms that the worker exposure to Parylene HT® dimer, are below the TLV-TWA set by ACGIH [redacted]

CBI 1

Environment

The production of Parylene HT® dimer requires the treatment of exhaust air and the management of solid /liquid wastes. To prevent leaching to the groundwater, the Galentis site area is fully impermeabilised and any rinse waters are collected separately and managed as liquid waste by the authorised external company by mean of incineration. To prevent leakage, the scrubbers are also equipped with containment tanks.

As required by the local Environmental legislation, an environmental monitoring scheme is place.

Exhaust air: any process fumes or gases coming from the water and/or glycol condensation systems of the reactors and vacuum pump assemblies are neutralised and removed by different scrubbers consisting of a multi-column suction and abatement system with recycling of the alkaline solution of water and caustic soda. Each Individual reactor is connected to the scrubbers by a closed system, while localised aspirators convey vapors/dust into the scrubber where not possible to operate in a full closed condition.

On six-monthly and annual basis, sampling is carried out at the stacks of the abatement systems by an accredited external laboratory, which will carry out the environmental analyses for the emissions.

According to the most recent monitoring [redacted], the air emission from the chimney is characterized as follows:

CBI 1

- Parylene HT® dimer: <Limit of Detection (LOD) [redacted]

The results have been further confirmed by the most recent monitoring [redacted] of the solid waste generated from the abatement solution generated from the scrubber, which is characterised as follows:

CBI 1

- Fluorine content:< Limito f Quantification (LOQ) [redacted];
- Parylene HT® dimer: <LOQ [redacted];
- Lower Heating Value (LHV): [redacted]

CBI 1

Solid and Liquid waste: Galentis approximately produces [redacted] (10-100) tons/month of industrial waste (including solid and liquid wastes).

CBI 1

With regard to the management of solid waste:

- Exhaust sails, generated from the intermediate stages of production are identified with the European Waste Code[8] (EWC) 07.07.10* "Other filtration residues and spent absorbents", placed in ADR approved steel drums, stored in a dedicated area, and subsequently sent to an authorised center for incineration.
- Different types of solid wastes, including packaging contaminated with the substance (bags) and used disposable PPE, etc., are also managed. Depending on the type, they are identified with the EWC 15.02.03 "Absorbents, filter materials, rags and protective clothing, other than those referred to in item 15.02.02*", or with 15.01.10* "Packaging containing residues of dangerous substances or contaminated by such substances", transferred from the production departments to dedicated containers for temporary storage, and subsequently sent to an authorised center for incineration.
- According to the most recent monitoring [redacted], the solid waste generated from the process is characterised as follows:
  - Fluorine content: [redacted];
  - Parylene HT® dimer: [redacted];
  - Lower Heating Value (LHV): [redacted]

CBI 1

With regard to the management of liquid wastes:

- Wastewater generated from process water contaminated by solvent, from the abatement solution of the scrubbers and from rainwater collected during the first 30 minutes of precipitation, are identified with the EWC 07.07.01* "Aqueous washing solutions and mother liquors", transferred from the production department to dedicated tanks for temporary storage, and subsequently sent to an authorised center for treatment/disposal for incineration.
- Organic solvents are identified with the EWC 07.07.08* "Other bottoms and reaction residues", transferred from the production department to dedicated tanks for temporary storage, and subsequently sent to an authorised center for treatment/disposal for incineration.
- According to the most recent monitoring [redacted], the liquid waste generated from the process is characterised as follows:
  - Fluorine content: [redacted];
  - Parylene HT® dimer: [redacted];
  - Lower Heating Value (LHV): [redacted]

CBI 1

3.4.1.3 Overview

Overall, the production process of Parylene HT® dimer is subject to a rigorous containment, which is achieved by the technical design of the process and the equipment aimed at preventing the releases for workers and environment. The efficiency of the containment measures for Parylene HT® dimer are further confirmed by the mass balance and by the occupational and environmental analytical monitoring, which is periodically carried out as required by the OSH and Environmental legislations.

With specific regard to the end of life, all the solid and liquid wastes generated from the production and contaminated with Parylene HT® dimer, are collected and disposed of by means of incineration.

3.4.2 Parylene HT® conformal coating process

The Parylene HT® dimer produced by Galentis, is supplied to different SCS sites involved in the conformal coating activities. The SCS sites are located both in and outside of the European Economic

[8] https://ec.europa.eu/eurostat/documents/342366/351806/Guidance-on-EWCStat-categories-2010.pdf/0e7cd3fc-c05c-47a7-818f-1c2421e55604

Area; with regard to the EEA, there are two Sites involved with conformal coating operations using Parylene HT®:

- Coating Center, Plzeň, Czech Republic;
- Coating Center, Pliezhausen, Germany;
- Coating Center, Dublin, Ireland (still not involved in the use of Parylene HT® dimer);

Two additional SCS sites involved in the conformal coating process of Parylene HT® dimer are located in Europe, but outside the EEA:

- Coating Center, Woking, United Kingdom;
- Coating Center, La Chaux-de-Fonds, Switzerland

Each site is involved in similar activities:

- Development of production process;
- Conformal coating of sampling part from costumers (also called Engineering runs or E-runs);
- Continued conformal coating of customers' parts.

The section below provides a qualitative description of the conformal coating process of the Parylene HT® dimer and the organisational and technical risk management measures in place at SCS's EEA sites to prevent and minimise the exposure to workers, general population and the environment.

3.4.2.1 Process description and risk management measures

Overall, the conformal coating of Parylene HT® dimer carried out at the SCS's sites in the EEA, consists of a CVP process of the Parylene HT® dimer, that leads to the polymerisation of Parylene HT® onto the material's / part's surface.

In general, chemical exposure to workers and emissions to the environment are prevented, assessed, and managed by means of organisational and risk management measures, as required by Regional, National, and European regulations related to OSH, Environmental, Product Stewardship and Quality, and by internal policies. All the SCS sites have adopted the ISO 9001 certification scheme to strengthen the quality management system.

The conformal coating process of Parylene HT® dimer, can be described as follow:

- **Loading:** The Parylene HT® dimer is received from Galentis together with the Safety Data Sheet (SDS), as solid powder packaged and sealed in two layers polyethylene (PE) anti-static bags (maximum 10 kg). Then, the dimer is manually scooped from the bag into a 'boat' (a horizontal cylindrical stainless steel container), which is weighed on a benchtop scale. The weight ranges from a few grams up to 1 kg, but typically a few hundred grams are sufficient for the conformal coating process. Finally, the "boat" and the dimer is manually transferred into the Parylene Deposition System (hereafter PDS), which is then closed. The PDS is also loaded with the material/part to be coated.

  The whole step takes around one minute. The personnel involved in weighing and transferring the dimer from the container to the scale and from the scale to the PDS, are equipped with protective gloves and Electrostatic Discharge (ESD) type coat, while no mask and located ventilation are considered necessary. According to the REACH Registration dossier, the 95.78% of the total particle size distribution of Parylene HT® dimer is > 75 µm, while 1.61% is < 45 µm; the occupational monitoring carried out on particulate exposure to workers during this step, has indicated that the generic Occupational Exposure Limits (OELs) for respirable and inhalable fraction are not exceeded neither during the weighing nor during transfer to the machines. With regard to the exposure to the vapor phase of Parylene HT® dimer, no monitoring or modelling data is available, but this is considered unlikely due to the chemical physical properties of the substance.

The extreme low exposure to workers is confirmed by ART (Advanced Reach Tool) modelling; nevertheless, to further reduce the possibility for release of particulate during this step, SCS is considering the installation of a ductless hood and the incineration of the filters.

All the empty bags and disposables potentially contaminated with the dimer, are managed as solid waste by means of incineration in the German Site, according to the local waste management requirements. For the other EU Sites, where the landfill is adopted according to the European waste management requirements, SCS is considering extending the voluntary incineration option.

- **Conformal coating:** The conformal coating process takes place entirely under the Vacuum system. The process starts with the Parylene HT® dimer in solid powder form and ends with the Parylene HT® Polymer film coated onto the material, through the Gorham Process.

  Figure 3-2 outlines the starting Parylene HT® dimer and final Parylene HT® polymer product.

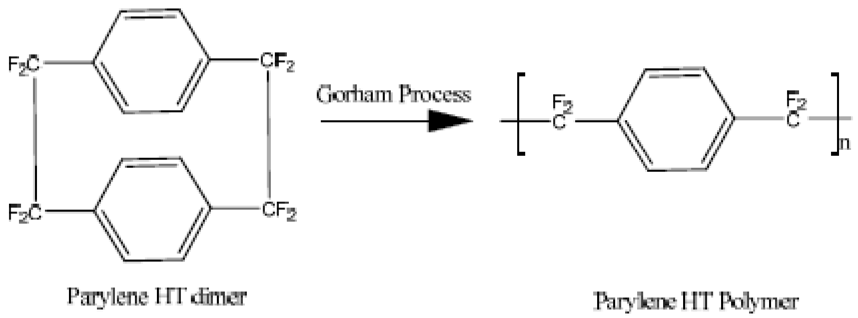


Figure 3-2 Gorham Process

Parylene coatings are applied at ambient temperatures with specialised vacuum deposition equipment. Parylene polymer deposition takes place at the molecular level, where films essentially ‘grow’ a molecule at a time.

Below, the single steps of the process are described in more detail:[9]

- **Sublimation:** In the first step of the process, the powdery raw material, called dimer, is heated. As the temperature approaches 150°C, the dimer sublimates into a gas without passing through a liquid state. At this point, the dimeric gas is ready to pass into the next stage of the deposition process.
- **Pyrolysis:** The dimer gas actually consists of two Parylene molecules, bonded together. In the pyrolysis stage, the gas is further heated in a furnace to temperatures as high as 700°C. The heat splits the molecules apart, creating a reactive monomer. That monomeric vapour is what becomes the Parylene conformal coating when it reaches the item to be coated in the deposition stage.
- **Deposition and Polymerisation:** The PDS containing the dimer and the items to be coated is depressurised to create a vacuum. The vacuum moves the vaporized dimer through the pyrolysis zone and into the deposition chamber. In that chamber, which is maintained at normal room temperature, the Parylene monomer vapor turns into a polymer, coating everything inside the deposition chamber. During the deposition process, the Parylene gas cools without having any meaningful heating effect beyond a few degrees on the items being coated.

[9] https://www.paryleneconformalcoating.com/conformal-coating-education-center/parylene-chemical-vapor-deposition/

Because Parylene is applied as a gas, the coating effortlessly penetrates crevices and tight areas on multi-layer components, providing complete and uniform encapsulation. Optimal thickness of the Parylene coatings is determined based on the application and the coating properties desired. While Parylene coatings can range in thickness from hundreds of angstroms to several mils, a typical thickness is in the microns range.

Figure 3-3 shows the three steps of the deposition during the coating process: vaporization, pyrolysis and deposition.

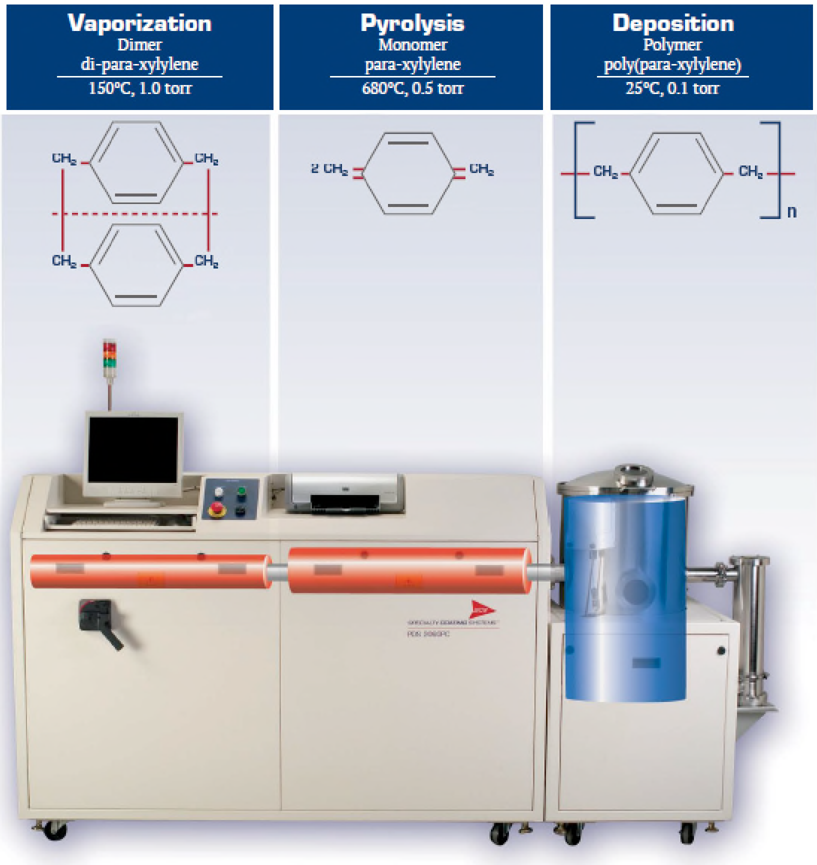


Figure 3-3 Parylene Vapor Deposition Polymerization (VDP)

- **Unloading of the coated materials / parts:** During the conformal coating process all the Parylene HT® dimer is consumed; the coated material/component is then unloaded from the deposition chamber, packaged and stored before the shipping to the costumers.

The potential for exposure to Parylene HT® dimer for workers and emissions to the environment during the coating process, either as dimer or monomer, are extremely low because of the technology behind the chemical vapour deposition process, which is a fully enclosed vacuum system. With specific regard to the exhaust containing Parylene, as the gas exits the chamber, a pump pulls it though a cold trap. That trap, which is usually cooled to extreme subzero temperatures, causes all the remaining Parylene to solidify so that the solid phase can be neutralised and disposed of as solid waste; following the neutralisation with a base, the waste still contains the CF2 group. As described for the loading phase, this waste flow is managed by means of incineration in the German Site, according to the local waste management requirements. For the other EU Sites, where the landfill is adopted according to the European waste management requirements, SCS is considering extending the voluntary incineration option.

3.4.2.2 Overview

Overall, with the exception of the loading of the Parylene HT® dimer into the PDS, which is carried out in open conditions for limited time and low quantities, and for which the monitoring of particulate results below the generic OEL, the coating process employing the Parylene HT® dimer can be considered a closed process where all the Parylene is consumed, with no or extremely low potential for exposure to workers and environment.

Regarding the waste management, the only solid wastes generated from the process are the package or disposables contaminated with Parylene HT® dimer and the solid by-product from the PDS's cold trap. These are currently collected and disposed of by means of incineration in the German site, while this is being considered as voluntary option also for the other European sites, where these solid wastes are currently managed by means of landfill.

3.4.3 Service life and End-of-Life

Service life

Despite the scientific literature about the Parylene family, no public available studies were identified regarding the potential for release of Parylene HT during the service life of the final product. However, SCS internal testing has confirmed that the chemical-physical properties confer stability under different conditions and prevent form degradation, as required by specific applications. Therefore, the release of degradation product is considered unlikely during the service life.

End-of-Life

The Directive 2008/98/EC (and following amendments, including the Directive 2018/851/EC), also known as Waste Framework Directive[10] (WFD), set the general framework and the targets for the prevention and the management of the waste in the EEA in order to protect the human health and the environment, with the exclusion of specific waste streams and in general of the industrial/non industrial emissions to air, water and soil. According to the waste hierarchy, Member States need to implement measures to meet higher targets for prevention, re-use, recycling, and the recovery of waste (including energy recovery), while the disposal (including landfill) should be taken as last option.

Similar to the principles that are applied over the whole life cycle of materials, the classification of waste as hazardous and non-hazardous drives the following management options; the classification of waste follows specific rules that can be done depending on the origin of the waste or depending on the content of hazardous components. The EU Member States and the local authorities have the authority to establish stringent management measures for hazardous wastes in case it is considered necessary.

Concerning waste flows, the EC has established also specific legislation based on the Extended Producer Responsibility Directive (EPRD) that further strengthen the framework and provide targets for the prevention and the management of the specific waste flows. This is the case, for example, for passenger/commercial vehicles, batteries and electric and electronic equipment.

Considering that SCS provides coating solution for components that are further assembled in complex products for different end users and for different EU markets, it is impossible to provide specific data regarding the end of life of such products.

Table 3-4 shows an overview of the End-of-Life legislation for each industry / market sector identified by SCS. A list of studies related to the End of Life of the specific industrial / market sector is also included.

[10] https://environment.ec.europa.eu/topics/waste-and-recycling/waste-framework-directive_en

Table 3-4 Overview of the End-of-Life legislation for each industry / market sector identified by SCS

Industry / Market sector	End of life legislations	Identified Bibliography
Electronics and semiconductors	Restriction of Hazardous Substances in Electrical and Electronic Equipment[11] (RoHS) and Waste from Electrical and Electronic Equipment[12] (WEEE) Directives - Ban of class of substances in materials - Specific target for recyclability and recovery to be achieved by the early design of material and the implementation of end-of-life management	- Alexandrov et al (2019), provides the monitoring of degradation products (low molecular weight PFAS) generating from the incineration of PTFE[13] - IATA (2018), commissioned a study to identify the most critical waste generating from the dismantling operation of aircraft. The PAMELA project demonstrated the possibility of recycling up to 85% of plane components, a significant advance on the earlier rate of 60%. These activities were carried out in response to the high number of planes that will be retired within the next few years and its environmental and economic impact[14]. - Patil et al (2022) provides an overview of the waste management of PBC (Printed Circuit Board)[15] - Coffin et al, 2023 provides and overview of the fate of PFAS from municipal solid waste disposed of in landfill[16] - The LIFE MED project implemented a new integrated management system for recovery of discarded medical equipment and biomedical devices in Italy.
Automotive / Transportation	End of Life Vehicle[18] (ELV) and Reusability, recyclability and recoverability[19] (RRR) Directives - Ban of class of substances in materials - Specific target for recyclability and recovery to be achieved by the early design of material and the implementation of end-of-life management	
Aerospace & Defence	WFD - Some major aircraft manufacturers are implementing EV-like approach on voluntary base	
Medical devices	WFD - waste that came in contact with biological fluids and identified as infective, are required to be incinerated	

[11] https://environment.ec.europa.eu/topics/waste-and-recycling/rohs-directive_en

[12] https://environment.ec.europa.eu/topics/waste-and-recycling/waste-electrical-and-electronic-equipment-weee_en

[13] Manuela Wexler. Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and Poly-Fluorinated Alkyl Substances (PFAS) in flue gas. Chemosphere, 2019 (226), 898-906

[14] IATA, Aircraft Decommissioning Study. 2018 https://webgate.ec.europa.eu/life/publicWebsite/index.cfm?fuseaction=search.dspPage&n_proj_id=2859#results

[15] Trunal Patil, Lara Rebaioli, Irene Fassi. Cyber-physical systems for end-of-life management of printed circuit boards and mechatronics products in home automation: A review. Sustainable Materials and Technologies, Volume 2020 (32)

[16] Ethan S. Coffin, Donald M. Reeves, Daniel P. Cassidy. PFAS in municipal solid waste landfills: Sources, leachate composition, chemical transformations, and future challenges. Current Opinion in Environmental Science & Health, 2023 (31)

[18] https://environment.ec.europa.eu/topics/waste-and-recycling/end-life-vehicles_en

[19] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32005L0064

Industry / Market sector	End of life legislations	Identified Bibliography
		This showed that it is possible to correctly treat medical waste, while reducing waste production and managing it by means of a specific characterisation of medical WEEE[17].

4. ANALYSIS OF ALTERNATIVES

4.1 Performance requirements of conformal coating

4.1.1 Functionality of PFAS in conformal coating

Parylene HT replaces the alpha hydrogen atom of the Parylene N dimer with fluorine (Figure 4-1). The resulting chemical structure confers greater electrical and mechanical properties, chemical inertness, long-term thermal stability at high temperature exposure to over 350° C (short - term at 450° C) and long-term UV exposure in comparison to the other Parylene variants and other thin coatings. Parylene HT also has the lowest coefficient of friction and dielectric constant, and the highest penetrating ability of the Parylenes.

Figure 4-1 Chemical structure of Parylene HT®

The main attributes that Parylene HT confers can be sumarised as below:

- Extreme thermal endurance (melting point >500° C)
- UV stability
- Barrier properties against chemicals and moisture.
- Low dielectric constant and dissipation factor
- Biocompatibility and biostability

End use temperatures of electronics continue to increase as miniaturisation of devices occurs and power requirements increase. Parylene HT has demonstrated to ensure low dielectric constant and dissipation factor, which are very relevant for radio-frequency (RF) electronics to preserve signal integrity and sensitivity. Likewise, Tin whiskers are a threat to reliability in lead-free assemblies and mitigation is important. In many electronic devices, operating temperatures have increased, lead-free solder has become more prevalent, while also being required to operate in high humidity, corrosive environments.

In general, the demands of the electronics industry are increasing towards the need for safer products, higher protection and higher reliability of various electronic components (pressure and temperature sensors, PCBs, MEMs, optoelectronic devices, fuel cell components and nanoelectronic parts, etc.). These requirements become more critical as electronic components become smaller and

[17] https://webgate.ec.europa.eu/life/publicWebsite/index.cfm?fuseaction=search.dspPage&n_proj_id=4991#results

more complex. Parylene HT has exhibited to be a suitable thin organic coating that can provide much-needed protection for advanced parts against harsh environments and is thermally stable at higher temperatures.

4.1.2 Technical feasibility criteria

As mentioned above, the most common attributes that impact electronics applications include chemical stress and moisture barrier, corrosion, UV exposure and extreme thermal exposure. Parylene HT has shown to be the most versatile to fulfil these requirements in comparison to the other Parylenes and even to other conformal coating options.

The key technical properties provided by Parylene HT are detailed below, which are sought to be fulfilled by any potential alternative.

4.1.2.1 Thermal stability

Parylene HT has shown not to degrade at the thermal levels encountered during the manufacturing of electronics, at temperatures up to 450°C. Parylene HT® has been demonstrated to survive continuous exposure to air at 350°C, with short exposure (less than 24 hours) to 450°, while Parylene N, Paryfree and Parylene C are expected to survive continuous exposure to air at 60°C, 60°C and 80°C, respectively, for 10 years and in oxygen-free atmospheres, or the vacuum of space.

Note that in automotive operating environments temperatures often range from -40° C to more than 350° C. Likewise, aerospace and defence applications are exposed to a wide range of temperatures. Parylene HT® coating provides thermal protection within harsh operating environments that span from the cryogenic levels of space (-150° C to -273° C) to extreme temperatures of 450°C.

4.1.2.2 UV stability

Although stable indoors, Parylenes N, C, D and ParyFree are not recommended for long-term use when exposed to direct sunlight (UV light). Parylene HT exhibits significant resistance to UV light, with no property degradation from accelerated exposures of up to 2,000 hours in air. Many aircraft devices, e.g., sensors in landing gears, are not in an enclosure so they are exposed to reflective UV, high humidity, corrosive atmospheric environments, and must function throughout the service life of the aircraft.

4.1.2.3 Low dielectric constant and dissipation factor

One of the features of Parylene coatings is that they can be formed in extremely thin layers. Parylenes, even in very thin layers, have excellent dielectric properties, withstanding voltages and show low dissipation factor. It has also been demonstrated that the voltage breakdown per unit thickness increases with decreasing film thickness. The low dielectric constant for Parylene HT in the gigahertz frequency range is often of great interest to designers of high frequency devices. Exhibiting the lowest dielectric constant among Parylenes, Parylene HT is particularly suited for these applications. Many electronics and components are used in critical areas with great demand on reliability.

4.1.2.4 Barrier properties and chemical resistance

Parylene HT® conformal coatings are excellent moisture and chemical barriers, providing protection against corrosive liquids, fluids, gases and chemicals. Parylene-coated electronics have been tested by an independent facility in accordance with the applicable requirements of IEC 60529, test conditions 14.2.7 and 14.2.8 for IPX7 and IPX8 designations, which demonstrate protection from harmful effects due to the ingress of water. The uncoated (control) electronics functionally failed during the test, but the Parylene-coated electronics passed both test conditions, functioning normally both during and after testing. These results indicate that Parylene conformal coatings are suitable to protect electronics and other devices against water splash and water immersion for more than 30 minutes at a depth of 1 m (IPX7) and 1.5 m (IPX8).

Parylenes resist chemical attack and are insoluble in all organic solvents at up to 150°C. Parylene coatings minimally swelled after exposure to a host of chemicals, including harsh automotive and aviation fluids (Table 4-2); however, the swelling completely reversed after the solvents were removed by vacuum drying. Additional testing indicated no changes in the films' physical or chemical properties.

Figure 4-2 shows a salt fog test performed on a Parylene HT® coated PCB (left side) and on uncoated PCB (right side). The salt fog test is an accelerated corrosion test in which specimens are exposed to a fine mist of a solution usually containing sodium chloride. Parylene HT® coated boards did not show any evidence of corrosion while the uncoated boards had salt and corrosion residue running vertically down the PCB.

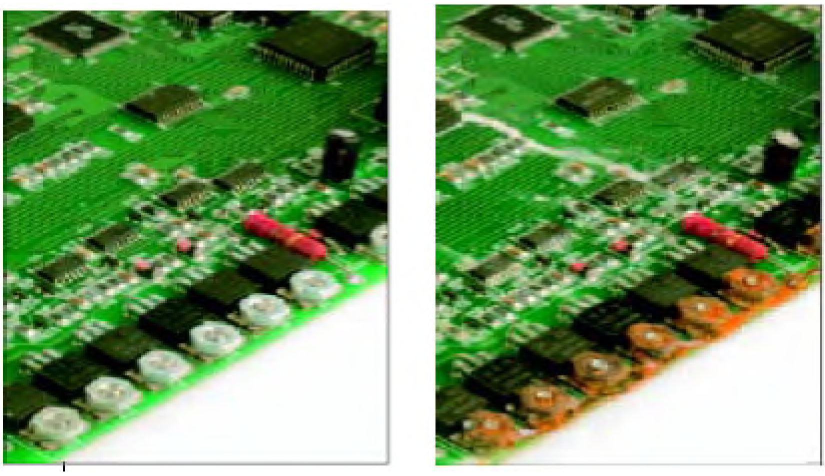


Figure 4-2 Parylene HT® coated (left side) and corroded uncoated PCB board (right side) after salt fog test. Taken from Kumar. R, et al[20].

4.1.2.5 Biocompatibility and biostability

SCS Parylenes N, C and Parylene HT have been tested according to the biological evaluation requirements. The biocompatibility and biostability of SCS Parylenes have been demonstrated in a wide range of medical coating applications over the past four decades.

For applications requiring biocompatibility, it is vital to clearly understand the level of biocompatibility required so that the optimum coating can be specified. Parylenes, used for decades on medical devices including long-term implants, satisfy the key aspects of ISO 10993, addressing a range of medical applications from surface and tissue contacting devices to long-term implants. In addition, SCS Parylenes N, C, Parylene HT and ParyFree are certified to comply with the biological testing requirements for US Pharmacopeia (USP) Class VI Plastics.

Likewise, Parylenes N, C, and Parylene HT have been tested with a variety of sterilisation methods, including steam autoclave, gamma and e-beam irradiation, hydrogen peroxide plasma and ethylene oxide. Post-sterilisation analysis evaluated the impact of these sterilising agents on Parylenes N, C and Parylene HT samples against unsterilised control samples. Electrical, barrier and mechanical properties were evaluated with results indicating these properties remained unchanged for most of the tests across these Parylene variants.

[20] Rakesh Kumar, F. Ke, A. Summers, L. Young. (2016). A high temperature vapor phase conformal coating for improving reliability of harsh environment electronics. 39th International Spring Seminar on Electronics Technology (ISSE). DOI:10.1109/ISSE.2016.7563174

4.1.2.6 Service life length

The electronics that use Parylene HT conformal coating are parts of devices that may have a service life spanning several years. Therefore, they must operate for at least as long as the longest expected service life of the final device. Also note that in terms of the transition to the circular economy, major emphasis is placed on equipment lasting longer and being able to be re-used and components being able to be recycled.

The coated devices or components must be sufficiently durable and resistant to corrosion and other chemical or environmental stress as well the continuous exposure to UV and high temperatures during operation and due to environmental exposure in some cases.

4.2 Efforts made to identify alternatives

In general, there are several methods of making electronic components and devices more reliable and protecting them from detrimental effects of both physical and operational environments. Among the several desired areas of improvements, manufacturers of electronics are looking at the protective materials, preferably in the form of thin film coatings with improved processing characteristics (e.g., hardness, lubricity), higher temperature integrity for potting, and even better dielectric strength.

Parylene coatings are known for their inertness, gas phase deposition, pinhole free, and excellent barrier properties. The need for having a more stable coating at higher temperatures with excellent electrical properties that can be deposited easily on various substrates has become more relevant for reduced-size electronics. Therefore, any effort to find alternatives to Parylene HT must fulfil these demands. Moreover, system reliability and efficiency of the electronics depend on the quality of materials, packaging and how these devices are used. The packaging of these devices involves material technology, manufacturing process, thermal management, and design optimisation related to various performances of the devices. Therefore, the desire for more reliable components and proper packaging is becoming more apparent as fewer field failures can be more cost efficient for manufacturers.

4.2.1 Approaches to identify alternatives

Literature review involved searching into scientific publications for alternative, primarily polymeric, coating materials for the various applications as described in section 3.1. The review also involved researching into the most critical properties (thermal and UV stability, dielectric properties, barrier properties and chemical resistance and biocompatibility) of the potential alternatives. The goal was to create a shortlist of materials that can be further investigated via testing to determine if they can be qualified.

Additionally, SCS research continues internally and with universities. Chemical modelling is used to identify potential chemical substances. To date, nothing has been identified that comes close to replicating the properties of Parylene HT.

4.2.2 Evaluation of identified alternatives

4.2.2.1 Parylene variants

SCS has carried a number of testing and experimental approaches to understand if the other Parylene variants may perform at the level that Parylene HT does when used to coat applications that demanded a greater level of protection for advanced parts against harsh environments, UV stability and thermal stability at higher temperatures. Therefore, physical and chemical property data is presented through comparison with the other coatings approaches and the commercially existing

Parylenes that have been assessed as potential alternatives. These findings are largely described by Kumar, et. al.[21] and are hereby presented in a concise manner.

Table 4-1 shows a comparative assessment of key properties displayed by the different Parylene variants and other traditional organic liquid coatings.

Generally, for electronics applications, moisture-insulation resistance tests are carried out in an accelerated manner to evaluate the resistance of conformal coatings to the deleterious effects of high temperature/humidity conditions.

Parylenes exhibit changes in mechanical properties with changes in temperature much as do other materials. As oxidative chain scission is the most important mode of degradation for Parylenes, freestanding films of Parylenes were physically analysed after exposure to constant elevated temperature in air circulating ovens for periods of weeks to months. In oxygen-free atmospheres or in the vacuum of space, the continuous service temperature projections exceed 200° C for both Parylene N and C, whereas Parylene HT has ability to resist thermal oxidation up to 450° C both in oxygen and oxygen-free atmospheres. Likewise, Parylene HT has shown to survive continuous exposure to 350° C in air without any adverse property change for more than 1,000 hours. The excellent thermal oxidative stability of Parylene HT in both air and inert environments is due to the stable carbon-fluorine bond in the polymer chain.

Another factor in oxidative degradation is UV radiation exposure. While the oxidation of Parylene N and C appears to be enhanced by exposure to UV radiation, Parylene HT has much higher resistance. When exposed to an accelerated UV stability testing per ASTM G154, Parylene N and C film survived less than 100 hours before yellowing or discoloration of the films occurred. However, Parylene HT film was stable without any change in appearance or other visual properties for more than 2,000 hours.

Parylene HT has shown to be excellent for use in electronics because of its bulk electrical properties. The dielectric constant and dielectric losses are very low and unaffected by moisture absorption. The bulk resistivities are advantageously high because of the purity of the Parylene HT its low moisture absorption, and in particular its freedom from trace ionic impurities. The typical electrical properties of Parylene HT are compared with other Parylenes and other organic liquid coatings in Table 4-1.

Generally applied much thinner than alternative liquid coatings, Parylene HT provides a pinhole-free barrier to protect against various fluids as well as moisture, chemicals and common gases.

[21] Rakesh Kumar, F. Ke, A. Summers, L. Young. (2016). A high temperature vapor phase conformal coating for improving reliability of harsh environment electronics. 39th International Spring Seminar on Electronics Technology (ISSE). DOI:10.1109/ISSE.2016.7563174

Table 4-1 Comparative key properties amongst Parylene variants and other traditional coatings

Property	Parylene N	ParyFree	Parylene C	Parylene D	Parylene HT®	Acrylic (AR)	Epoxy (ER)	Polyurethane (UR)	Silicone (SR)
Thermal stability									
Continues service (°C)	60	60	80	100	350	82	177	121	260
Short term service (°C)	80	80	100	120	450	-	-	-	-
UV stability (hour of exposure)	Less than 100	-	Less than 100	-	>2,000	-	-	-	-
Dielectric constant									
60 Hz	2.65	2.38	3.15	2.84	2.21	-	3.3 - 4.6	4.1	3.1 - 4.2
1 KHz	2.65	2.37	3.10	2.82	2.20	-	-	-	-
1 MHz	2.65	2.35	2.95	2.80	2.17	2.7 - 3.2	3.1 – 4.2	3.8 - 4.4	3.1 - 4.0
Barrier properties									
Water absorption (% after 24 h)	Less than 0.1	Less than 0.1	Less than 0.1	Less than 0.1	Less than 0.1	0.3	0.05 – 0.10	0.6 -0.8	0.1

Note: Test methods and / or literature reference can be found in Kumar et. al.[22] *and SCS Parylene Properties*[23].

[22] Rakesh Kumar, F. Ke, A. Summers, L. Young. (2016). A high temperature vapor phase conformal coating for improving reliability of harsh environment electronics. 39th International Spring Seminar on Electronics Technology (ISSE). DOI:10.1109/ISSE.2016.7563174

[23] Technical Library | Specialty Coating Systems (scscoatings.com)

Table 4-2 shows that Parylene HT films minimally swelled with exposure to automotive chemicals and fluids; however, the swelling completely reversed after the solvents were removed by vacuum drying.

Table 4-2 Chemical and fluid resistance of Parylene HT®

Chemical	Parylene HT® film swelling
Automotive Fluids Heated to 90°C Antifreeze - 50% solution Engine Oil - 10W30 Transmission Fluid - Dexron Ill Mercon	< 2.5%
Automotive Chemicals Heated to 75°C Nitric Acid - 10% and 70% solutions Sulfuric Acid - 10% solution Sulfuric Acid - 95% - 98% solution	< 1%
Automotive Fluids at Room Temperature Brake Fluid - DOT 3 Power Steering Fluid Windshield Washer Fluid Unleaded Gasoline - 87 Octane Diesel Fuel	< 1.5%

This comparative assessment indicates that Parylene HT is an excellent coating material for meeting the growing requirements of protection and reliability of advanced electronics and components. Parylene HT is well suited for electrical and environmental protection of various micro and nano electrical components, biosensors, printed circuit boards and other electronic components operating under many high temperature application conditions. Parylene HT is also suitable for contamination and corrosion control, dry lubrication and protection of high density and highspeed integrated circuits.

4.2.2.2 Plasma coating and Liquid coating alternatives

Plasma coating and various traditional organic liquid coatings have been evaluated and some experimentally assessed for their suitability to meet the technical requirements that Parylene HT conformal coating confer to the application in scope. Table 4-3 summarises these findings, provides a description of the alternative, assess and concludes on its suitability to substitute Parylene-HT conformal coating.

Table 4-3 List of plasma coating and traditional organic liquid coatings potential alternatives evaluated by SCS

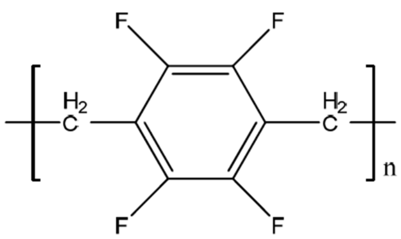
Alternative name	Level of assessment	Identification / Description	Discussion on suitability	Conclusion
Plasma coating				
	Literature review	Plasma is an energy-rich gas state that can be used to modify the surface of the product to improve its performance. Plasma technology is based on a simple physical principle. Matter changes its state when energy is supplied to it. Solids become liquid, and liquids become gas. If additional energy is then fed into a gas by means of electrical discharge it eventually ionises and goes into the energy-rich plasma state, the fourth state of matter[1]	Coatings applied by plasma can change surface characteristics to meet special product requirements that include: Adhesion promotion Corrosion protection Hydrophobic Barrier (Gas and liquid) Electrically-conductive Hydrophilic Anti-adherent Depending on the application, plasma coating deposits a coating down into the microstructures of the material surface. This can be highly effective for electronic circuit boards[24].	Not suitable. Does not provide UV-stability and high temperature stability
Organic liquid coatings				
Acrylic Resin (AR)	Literature review and experimental comparison with Parylene HT	The following are the application methods for traditional conformal coatings: **Manual spraying** - Conformal coating can be applied with an aerosol can or handheld spray gun. It is generally used for low volume production when capital equipment is not available. This method can be time-consuming because areas not requiring coating need to be masked. Also, quality and consistency of outcome are operator-dependent, so variations are common from board to board.	Acrylic conformal coating provides fair elasticity and general protection. Acrylic conformal coating is recognised for its high dielectric strength, and fair moisture and abrasion resistance. What generally distinguishes acrylic coating from other resins is its facility for removal. Acrylic coatings are easily and quickly removed by a variety of solvents, often without requiring	Not suitable. It only offers dielectric strength, but no other requirement (e.g., Thermal stability, and UV stability) is met

[24] SCH Technologies. How can plasma treatment help my conformal coating process? Online publication How can plasma treatment help my conformal coating process? - Conformal Coating UK

Alternative name	Level of assessment	Identification / Description	Discussion on suitability	Conclusion
		Automated spraying – A programmed spray system that moves the board on a conveyor under an alternative spray head that applies a conformal coating. **Selective coating** - An automated conformal coating process that uses programmable robotic spray nozzles to apply the conformal coating to very specific areas on the circuit board. This process is used in high volume processes and can eliminate the need for masking. An applicator may have a built-in UV lamp to cure coating immediately after it is applied. **Dipping** - The circuit board is first immersed, then withdrawn from the conformal coating solution. Immersion speed, withdrawal speed, immersion time, and viscosity determine the resulting film formation. It is a common conformal coating technique for high volume processing. A great deal of masking is generally required before the coating process. Dipping is only practical when coating on both sides of the board is acceptable. **Brushing** - Brushing is a simple application technique used mainly in repair and rework applications. The conformal coating is applied with a brush to specific areas on the board. It is a low-cost method, but it requires a lot of manual labor and is highly variable depending on operator proficiency and consistency This method is best suited for small production runs[25]	agitation. This makes rework and even field repair very practical and economical. On the other hand, acrylic coatings do not protect against solvents and solvent vapours, which could result in less-than-ideal performance for an application that involves harsh environments. Acrylic coatings can be considered basic, entry-level protection, because they are economical and protect against a broad level of contamination. However, they are not the best-in-class for any characteristic except possibly dielectric strength. [11]	
Silicone Resin (SR)	Literature review and experimental comparison with Parylene HT		Silicone conformal coating provides excellent protection in a very wide temperature range. SR provides good chemical resistance and salt spray resistance and is very flexible. Silicone conformal coating isn't abrasion resistant because of its rubbery nature, but this property	Not suitable Doesn't offer abrasion resistance, it's highly porous, results in thicker coatings and is less conformal in

[25] Techspray. The essential guide to conformal coating. Online publication Essential Guide to Conformal Coating \| Techspray

Alternative name	Level of assessment	Identification / Description	Discussion on suitability	Conclusion
			does make it resilient against vibrational stresses. Silicone coatings are commonly used in high-humidity environments. Special formulations that can coat LED lights without colour shift or reduction of intensity are available and make SR conformal coatings a popular choice for applications such as outdoor signs. Removal can be challenging, requiring specialised solvents, long soak time, and agitation from a brush or an ultrasonic bath[2]	comparison to Parylene HT.
Urethane (Polyurethane) Resin (UR)	Literature review and experimental comparison with Parylene HT		Urethane conformal coating is known for its excellent moisture and chemical resistance. It is also very abrasion resistant. Combining those factors with its solvent resistance results in a conformal coating that is very difficult to remove. Like silicone, full removal generally requires special solvents, long soak time, and agitation with a brush or an ultrasonic bath. Urethane conformal coating is commonly specified for aerospace applications where exposure to fuel vapours is a common concern.[11]	Not suitable at high temperatures
Other coatings				
Epoxy Conformal Coating	Literature review and experimental comparison with Parylene HT		Epoxy resins (ER) are usually available as two-part compounds and create a very hard coating. Epoxy conformal coatings provide very good humidity resistance and are not generally permeable, unlike traditional conformal coatings. They also have high abrasion and	Not suitable Hard coating Does not meet UV-resistance and high temperature resistance

Alternative name	Level of assessment	Identification / Description	Discussion on suitability	Conclusion
			chemical resistance. Typically, they are very difficult to remove once cured and are not as flexible as the other materials. Epoxy coatings are common in potting compounds, which in contrast to conformal coatings, completely cover the electronics in a solid and level layer of material. [11]	
Thin Film / "Nano" Coatings	Literature review	A coating is dissolved in a carrier solvent and applied with a spray or dip method to create a very thin coat, although not at a nanometer scale as the nickname suggests. [11]	They are commonly used to provide a minimal amount of hydrophobicity, which may prevent losses from very quick exposure to water. This type of coating does not offer the level of surface protection that other coating methods do. [11]	Not suitable Does not meet any requirement and carrier solvents are frequently fluorocarbon-based
Parylene F/VT-4	Literature review and experimental comparison with Parylene HT	The placement of fluorine atoms in Parylene HT is on alpha carbons (side chain fluorine – see figure 4.1) while in Parylene F fluorine atoms are on the benzene ring (see below chemical structure). 	Parylene HT coating provides a much better protection and reliability enhancement than Parylene F coating of electronics and medical devices application when exposed to high temperature and/or outdoor environments. Thermogravimetric analysis demonstrate that Parylene F undergoes thermal degradation earlier than Parylene HT. Parylene HT, with the high stability of C-F bonds, has enhanced thermal stability and thermal oxidative stability. In ASTM G154 testing (UV stability test) Parylene F coating discolored, cracked and flacked off the substrate earlier before 750 h while Parylene HT survived 2000 h without any changes. SCS worked on a project with a customer to compare Parylene F	Not suitable Does not meet temperature and UV stability requirements.

Alternative name	Level of assessment	Identification / Description	Discussion on suitability	Conclusion
			and Parylene HT perfomance at high temperature. Both Parylenes were subject to a continuous temperature rating of 200° C (1000 h) and a short-term rating of 350° C (1000 h). The customer's internal testing failed electrical tests after 1000 h at 200° C when devices were coated with Parylen F, while Parylene HT maintained performance.	

4.2.3 Overall conclusions on available alternatives

Overall, it is clear that none of the potential alternative materials and technologies are currently suitable to substitute Parylene HT in the conformal coating of electronics uses in applications in industry sectors such electronics, automotive, aerospace & defence and some medical applications. While some of the alternatives can offer corrosion protection such as plasma coating, mechanical flexibility (resin coating), dielectric strength (acrylic resin), there is no alternative that meets all requirements, including thermal and UV stability, mechanical flexibility and as they require the combination of thermal and UV stability with barrier/chemical resistance properties and dielectric properties.

A PFAS-free alternative in conformal coatings would require extensive research and testing before their technical feasibility can be assessed, as they are primarily used on applications that do not require both UV and thermal resistance or other combined feasibility criteria.

As a conclusion, SCS and Galentis consider that, at the time of writing, there are no technically suitable alternatives to their currently uses in conformal coating.

Table 4-4 summarises the evaluation of the identified potential alternatives and concludes that they partially fulfil the required technical requirements to perform at the level that Parylene-HT conformal coating does.

Table 4-4 Assessment of shortlisted, potentially suitable alternatives

Alternative	Technical requirement				
	Thermal stability	UV stability	Barrier properties and chemical resistance	Low dielectric constant and dissipation factor	Biocompatibility
Parylene HT®					
Parylene variants					
Plasma coating					
Acrylic Resin (AR)					
Silicone Resin (SR)					
Urethane(Polyurethane) Resin (UR)					
Epoxy Conformal Coating					
Thin Film / “Nano” Coatings					

Green box - met requirement; Orange box - partially met requirement but not at Parylene HT® level; Red box - not met requirement

4.3 Substitution plan

4.3.1 Actions and timeline required for substitution

SCS estimates that, considering the current situation, with no non-PFAS alternatives currently available, it could take **minimum 10 years** before substitution is possible.

The substitution process can be broken down in the following high-level phases:

Phase 1 – Development of alternative molecule, lab scale manufacturing, initial trials and process development (minimum **5 years**): SCS needs to carry out extensive research to identify the most likely substitution candidates, before assessing their technical feasibility. Each iteration with an alternative or set of alternatives can take up to five years, and includes evaluation of each alternative at component, module and end-application level.

1.1. Development of alternative molecule (3 - 5 years per iteration)

  a) Assess whether the potential alternatives meet specifications. (e.g., resistance to high temperature, UV stability, electrical and barrier properties humidity, etc.)

  b) In case a suitable alternative is not identified, repeat previous iterations until a suitable alternative candidate is available on material level.

1.2. Lab scale manufacturing and process development (1 - 2 years)

  a) Modify process (material application, baking time and temperature, storage) to produce conformal coatings with required properties and performance.

1.3. Initial trials (1 - 2 years)

  a) Perform experimental testing (initial tests on representative PCBs and other applications, decomposition and lifetime, etc…)

  b) Refine / make changes to material composition based on test results gathered.

  c) Go back to phase 1.1 if the candidate is not a suitable option to pursue further.

Phase 2 - Qualification in products and customer acceptance (**3 - 6 years**): once an alternative has been developed and validated in SCS's process, the new conformal coating will need to be tested in the customers' products to assess whether it delivers the customer's product specifications. It will be necessary to run an intensive qualification programme to cover all potential failure modes.

2.1. Reliability tests (internal) (approximately 1- 2 year)

  a) Life-time tests

  b) Environmental stress tests

2.2. End-product qualification (customer site) (1 – 2 year)

2.3. Phase-out of existing material (component, WIP, end-product) (1 - 2 year)

It must be noted that, if anywhere on the process there is a result that results in the currently assessed alternative not being technically feasible, the development process will need to move to previous steps to modify the process or the material composition. If these modifications do not succeed, it is possible that the process will move all the way to the beginning, with the selection of a different potential alternative.

4.3.2 Factors affecting substitution

As discussed in Section 4.2, currently there are no technically feasible alternatives for conformal coating fulfilling the technical criteria at the level that Parylene HT provides.

The main difficulty is to identify a non-fluorinated alternative that can display high thermal and UV stability to ensure a trouble-free service life of electronics and medical applications. The alternative conformal coating process must ensure to offer extreme thermal endurance (>200° C) , UV stability, barrier properties against chemicals and moisture, low dielectric constant and dissipation factor and for some medical applications biocompatibility and biostability.

The alternatives discussed in Section 4.2.2 are not currently suitable and / or would require a completely different technology than the one currently in use by SCS. Therefore, it is not certain that an alternative can be identified with the first development iteration. This could set the substitution plan back for an additional three years or even longer.

The minimum 10-year duration mentioned in Section 4.3.1 assumes that there will not be any other unexpected delays, e.g., due to issues such as supply chain disruptions or failure to meet a customer's validation testing.

5. DEROGATION SCENARIO

5.1 Conformal coating is not described as a use by the restriction submitters

SCS was not able to find references to conformal coating process as a use category / subcategory in the proposed PFAS restriction document. SCS also did not find that the submitters described uses of PFAS substances in conformal coating as a thin polymeric film protective layer applied to printed circuit boards (PCBs). The same appears to be true for the coating of medical devices, where there is no specific reference to conforming coating in this category/sub-category of use.

Although in Table 2 (PFAS main applications and sub-uses) of the restriction proposal document (page 53)[26] there is a mention about the use of PFAS substances in coating applications of electronic components in the use category: electronics and semiconductors, it is not certain if this refers to the use of fluorinated Parylene in the process of conformal coating to protect electronic components and enhance their performance in certain conditions. It should be noted that in a related study, it is acknowledged the use of fibre-reinforced fluoropolymer layer in PBC to achieve low dielectric constants and allow for the separation of high voltage components [27].

Therefore, SCS would like to request authorities to consider the following use within the scope of the PFAS restriction proposal:

- **Use of Parylene HT® dimer (CAS 3345-29-7) in the process of conformal coating in applications for electronics and medical devices when operative performance is required to be maintained at a wide range of extreme temperatures (-40°C to higher than 350°C) and/or with long-term UV exposure.**

5.2 Proposed derogation(s) and request for additional derogations

5.2.1 Medical devices related derogation

SCS believes the use of Parylene HT in conformal coating of medical devices can be considered covered by the derogation as marked as for "reconsideration as outlined in the condition of restriction [20]:

- *"The following potential derogations are marked for reconsideration after the Annex XV report consultation:*

[26] Annex XV reporting format 040615 (europa.eu)

[27] Juliane Gluge, Martin Scheringer, Ian T. Cousins, Jamie C. DeWitt, Gretta Goldenman, Dorte Herzke, Rainer Lohmann, Carla A. Ng, Xenia Trieri and Zhanyun Wangj. (2020). An overview of the uses of per- and polyfluoroalkyl substances (PFAS). Environ Sci Process Impacts1;22(12):2345-2373. doi: 10.1039/d0em00291g.

j. [coating applications for medical devices other than Metered Dose Inhalers until 13.5 years after EIF];".

Indeed, the restriction submitters acknowledge that there is weak evidence that technically and economically feasible alternatives are not available (see below).

"*Given the weak evidence that technically and economically feasible alternatives are not available at EiF, the following potential derogation is marked for reconsideration after the Annex XV report consultation: • [Coating applications for medical devices other than Metered Dose Inhalers (MDIs)]"*

With the information provided in this report (section 4), SCS wanted to highlight that despite over 20 years of R&D they are still working to find alternatives that provide the same level of protection to medical devices (and other applications) as Parylene HT conformal coating does.

In medical devices applications Parylene HT offers additional low coefficient of friction where lubricity is important. It also provides superior performance when compared to other non-PFAS Parylene variants to protect the patient's body from electric impulses and other functional inevitabilities – vibrations, etc. – that are required from efficient operation, while safeguarding the device itself from often harsh bodily fluids.

Parylene HT is also the preferred choice for medical electronics. Parylene HT is remarkably stable biologically, chemically and electronically, which provides an effective electrical insulator that will not degrade in the presence of electrical current. It resists solvents and is insoluble at temperatures to 150°C. These factors generate reliable consumer safety under most performance circumstances. as for over

5.2.2 Transport vehicles derogation

On the other hand, SCS also understands that the use of Parylene HT based conformal coating in electronic components of transport vehicles should be covered by the below derogation, given that the proper functioning of many electronic components relies on high quality coating that consequently contributes to the safety of vehicles.

o. [applications affecting the proper functioning related to the safety of transport vehicles, and affecting the safety of operators, passengers or goods until 13.5 years after EiF].

Automotive operating environments often range from -40°C to higher than 350°C. In addition, many applications also experience prolonged exposure to UV light. It is evident that components not performing at these harsh conditions would compromise safety of vehicles. With the accelerated development of electric, hybrid and fuel cell technologies, Parylene HT conformal coating has been demonstrated to offer exceptional dielectric properties, ensuring that the high level of power required for operating these electronic systems will not be weakened or distorted. For all these SCS supports the need of this proposed derogations and believes Parylene HT conformal coating should be covered by it.

5.2.3 Request for a specific derogation

This report has provided evidence that there are currently no alternative materials or technologies ready to substitute Parylene HT in the conformal coating in applications in industry sectors such as electronics, automotive, aerospace & defence and some medical applications. While some of the alternatives can offer corrosion protection, mechanical flexibility and dielectric strength, there is no alternative that meets all requirements, including thermal and UV stability and mechanical flexibility. As many applications require the combinations of thermal stability with barrier/chemical resistance properties and dielectric properties, this is a critical selection criterion. SCS believes that, considering the current situation, with no non-PFAS alternatives currently available, it could take more than a decade before substitution is possible, as described in Section 4.3.

Therefore, SCS would like to request the authorities to consider the following **specific derogation:**

- **Derogation for the use of Parylene HT® dimer (CAS 3345-29-7) in the process of conformal coating in applications for electronics and medical devices when operative performance is required to be maintained at a wide range of extreme temperatures (-40°C to higher than 350°C) and/or with long-term UV exposure.**

5.3 No derogation scenario

5.3.1 Socioeconomic impact

In a no derogation scenario, in which the restriction will apply fully, SCS and Galentis would lose their business that relies on Parylene HT coating. That is, Parylene HT® dimer would not be able to be produced and commercialised by Galentis, and SCS would not be able to offer the Parylene HT conformal coating service to their customers. As a consequence, SCS and Galentis business would be downsized by 10% to 20%, which is basically leading to the decision of shutting down the product lines in scope (with loss of respective sales) but continue other operations.

In this scenario, no plant resizing is expected to occur; however, capital equipment would be underutilised. In addition, a financial impact to the four EEA sites should be anticipated as a result of the loss of manufacturing and sales, which consequently would result in redundancies in the EEA. It is eventually unlikely to be able to transfer workers to a different plant or production line to avoid redundancies because the EEA sites are in different countries, which would require employees to relocate. Historically, when the business has moved, employees do not relocate, ultimately resulting in increased costs due to having to hire and train new employees.

SCS also considers that loss of product sales would not be gained by the competition since currently there are no replacement products in the market that can perform at the level the Parylene HT coated products do. SCS identifies about 6 main competitors in the market segment of Parylene HT coating, all of them Chinese competitors. However, it is evident that they will be equally impacted by a PFAS restriction in the EEA. It should be noted that SCS leads the EEA market with about 95% of share.

It is difficult for SCS to estimate the overall impact of the proposed PFAS restriction would cause on their customers. The total value of the coated devices could be 100 to >1000 times the cost of the coating. Likewise, the total value of the end use completed product where the device is used could be 1 million times the cost of the coating (SCS revenue), e.g., military aircraft.

If SCS were to halt production/sales while it works to develop a PFAS-free coating alternative (providing a comparable level of performance to Parylene HT), it is unclear if it could enter the market in the future. It should be noted that the current coating process with Parylene HT took about 10 years to establish market share after initial development and the entire process took about 15-20 years. Thus, in the event of having to stop production, sales would be minimal and at the same time large development costs would be incurred, which would cause weakness in the entire business segment and it would most likely not be able to return to the market.

5.3.2 Societal costs associated with refused derogations

SCS believes that the absence of a derogation to allow the continued and limited use of Parylene HT® dimer in the conformal coating could result in the following societal impacts:

- A reduction of reliability and durability of electronic components and systems, that will also compromise:
  - the performance of final EEE (Electrical and Electronic Equipment);
  - the performance and safety of the vehicles and of defense instruments and assemblies; and
  - medical devices placed on the market in the EEA, whose systems might be subject to early failure.
  - Likewise, there will be an inability to service and repair existing products.

- A reduction of the quality and standard of health services, since more invasive surgeries and medical devices might be required as an alternative, with the increasing risk of cross infection for patients.

The Table 5-1 summarises the potential societal impact associated with a non-derogation scenario for the use of Parylene HT conformal coating.

Table 5-1 Potential societal impact associated with the non-derogation scenario

Applications of Parylene HT conformal coating	Societal dimensions impacted by the non-derogation scenario			
	Health	**Safety**	**Protection**	**Repair**
Electronics				
Automotive / Transport				
Aerospace and Defence				
Medical devices				

6. CONCLUDING REMARKS

The conclusions from this study are that:

1. **There are currently no PFAS-free alternatives to Parylene HT conformal coating that can ensure that electronics components can remain operative under harsh conditions such as UV exposure and can remain thermally stable at higher temperatures.**

None of the potential alternative materials and technologies evaluated by SCS are currently suitable to substitute Parylene HT in the conformal coating of electronics uses in applications in industry sectors such as electronics, automotive, aerospace & defence and some medical applications. While some of the PFAS-free alternatives can offer corrosion protection (e.g., plasma coating), mechanical flexibility (resin coating) or dielectric strength (acrylic resin), there is no alternative that meets all requirements, including thermal and UV stability, mechanical flexibility and that can therefore be used in the many applications that require the combination of these properties.

A PFAS-free alternative in conformal coatings would require extensive research and testing before their technical feasibility can be assessed, as they are primarily used on applications that do not require both UV and thermal resistance or other combined feasibility criteria.

2. **SCS and Galentis can ensure that any potential PFAS emissions are fully controlled in their manufacturing operations**

SCS has locations across the globe. Headquartered in Indianapolis, SCS has nine coating centers in North America, seven coating centers in Asia and five coating centers in Europe: the UK (non-EEA), Ireland, Czech Republic, Germany, and Switzerland (non-EEA). All five sites in Europe are multi-purpose coating centers and ISO 9001 certified facilities.

The production process of Parylene HT® dimer is subject to rigorous containment, which is achieved by the technical design of the process and the equipment aimed at preventing the releases for workers and environment. The efficiency of the containment measures for Parylene HT® dimer are further confirmed by mass balance data and by occupational and environmental analytical monitoring.

All solid and liquid wastes generated during production that are contaminated with Parylene HT® dimer, are collected and disposed of by means of incineration.

The coating process employing the Parylene HT® dimer is a closed process where all the Parylene is consumed, with no or extremely low potential for exposure to workers and environment.

3. SCS request for a specific time limited derogation for the use of Parylene HT® dimer in the conformal coating process

As there are no suitable alternatives for the applications where Parylene HT is used in, and the time needed for developing a suitable alternative could take more than ten years, SCS would like to request the consideration of the following specific derogation**:**

Derogation for the use of Parylene HT® dimer (CAS 3345-29-7) in the process of conformal coating in applications for electronics and medical devices when operative performance is required to be maintained at a wide range of extreme temperatures (-40°C to higher than 350°C) and/or with long-term UV exposure.

SCS believes that the absence of a derogation to allow the continued and limited use of Parylene HT® dimer in the conformal coating could result in the following societal impacts:

- A reduction of reliability and durability of the electronic components and systems, that will also compromise: i) the performances of final EEE (Electrical and Electronic Equipment); ii) the performances and the safety of the vehicles and of defense instruments and assemblies, iii) and medical devices placed on the market in the EEA, whose systems might be subject to early failure. Likewise, there will be an inability to service and repair existing products.
- A reduction of the quality and standard of health services, since more invasive surgeries and medical devices might be required as an alternative, with the increasing risk of cross infection for patients.

ANNEX – JUSTIFICATIONS FOR CONFIDENTIALITY CLAIMS

Blanked out item reference	Justification for confidentiality
CBI 1	**Demonstration of Commercial Interest:** Proprietary manufacturing and specification information are closely held to prevent competitors from replicating procedures and procedures conditions. These details are only shared under strong non-disclosure agreements and are not made publicly available. **Demonstration of Potential Harm:** If process information were to be revealed, competitors could try to copy the design and process, leading to loss of knowhow and market position. Even a portion of the full process information or the applicant's specifications could be used to "reverse engineer" the process. **Limitation to Validity of Confidentiality:** This claim is valid indefinitely
CBI 2	**Demonstration of Commercial Interest:** Information on business commercial performance, such as manufacturing output, sales, type of products, revenue and profit margins, are commercially sensitive information and are only supposed to be known by the company. Volumes of PFAS used are confidential information that are only to be used for the applicant's planning and operations If they become publicly available they will distort competition and may even be in breach of anti-trust laws in the UK and the EU. **Demonstration of Potential Harm:** If marketing (production, sales, type of products, revenue and profits) information were to be released, it will provide the applicant's competitors with proprietary knowledge of information on the applicant's market share and would give them an unfair competitive advantage. **Limitation to Validity of Confidentiality:** This claim is valid indefinitely