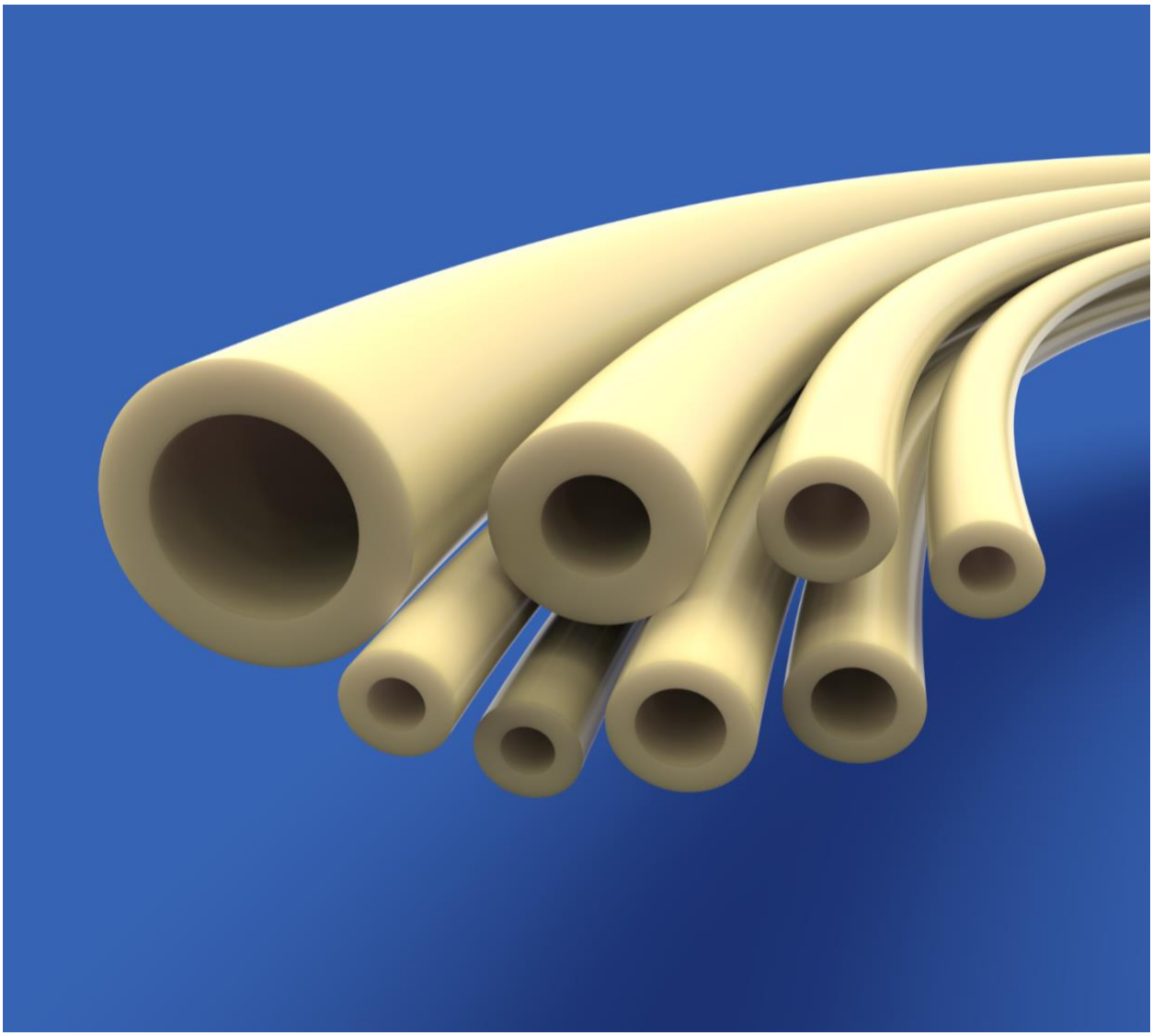
ELDON JAMES

Validation Guide

EJPrene



ELDON JAMES

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1. VALIDATION GUIDE OVERVIEW

1.1. Introduction

The purpose of this validation guide is to document the testing and results of the EJPrene tubing line. It will provide users with the information necessary to assess the suitability of these products for use in their intended applications. The testing and results to follow will detail the mechanical, material, performance, environmental, leachables and extractables, and other USP tests required to provide users with the information necessary to assess the suitability of these products for use in their intended applications.

1.2. Scope

EJPrene is an opaque, thermoplastic vulcanizate (TPV) tubing that contains no animal derived materials, plasticizers, natural rubber latex, or vinyl acetate. It is primarily designed to be used in peristaltic applications but can also be used in food, beverage, bioprocess, and medical device applications, to name a few. It has excellent room temperature compression set properties, is biocompatible, and has good chemical resistance. It is temperature stable from -50°C to 135°C (-58°F to 275°F) and can be sterilized by autoclave, ethylene oxide or radiation.

EJPrene exhibits very low extractables and does not contain phthalates or halogens. It is manufactured according to GMP and meets USP Class VI requirements. EJPrene exhibits similar properties as rubber and is the first choice as an alternative to Santoprene™.

1.3. Effective Date

The information contained within this document is current as of March 2022.

1.4. Country of Origin

EJPrene tubing is manufactured in the U.S.A.

1.5. Product Manufacturer

EJPrene is manufactured by:

Eldon James Corporation
10325 East 47th Avenue
Denver, Colorado, 80238

Eldon James Corporation
3486 Precision Drive
Fort Collins, CO 80528

1.6. Manufacturing Environment

EJPrene is manufactured in an ISO Class 7 cleanroom environment within a facility certified to both ISO 9001:2015 and ISO 13485:2016.

1.7. Materials of Construction

EJPrene is a proprietary formulation within the TPV family. Eldon James considers certain information regarding the manufacture of its materials, products, and assemblies as confidential and internal intellectual property.

1.8. Summary of Material Specifications

Mechanical		
	Density	0.95 gr/cm^3
	Hardness	70A
Thermal		
	Continuous Service Temperature	-58°F to +275°F (-50°C to +135°C)
	Glass Transition Temperature	-88°F (-67 °C)
Application Specific		
	Steam Autoclavable	121 °C, 132 °C, and 134 °C cycles
	Radiation (1)	≤45 kGy (Gamma and E-beam)
	EtO	Standard cycle 7 and 8
	Compression Set	17% 73 °F (23 °C), 22 hr 18% 73 °F (23 °C), 168 hr +41% ≥158 °F (70 °C), ≥22 hr

(1) Color may shift at higher radiation doses.

Table 1.8: Summary of Material Specifications

2. REGULATORY INFORMATION

2.1. Allergens/ Plant Derived Components

To the best of our knowledge based on the information provided to us by our raw material supplier and their formulation reviews are not utilized in this product: Celery, cottonseed, crustacean shellfish, eggs, fish, legumes, lupin, milk, mollusks, monosodium glutamate (MSG), mustard, peanuts, seeds (e.g. poppy, sesame, sunflower), sulfites, tree nuts (eg., almonds, pecans, walnuts), and wheat (gluten). Note: This product utilizes raw material(s) which contain additives with material derived from palm or soybeans.

2.2. Ozone Depleting Chemicals (ODCs)

Complies with Class I/Class II ozone layer depleting substances as listed in the Clean Air Act of 1990 and 1005/2009/EC in the manufacture or formulation of this product; not known or expected to be present based on the final product composition and raw ingredients.

2.3. Materials from Genetically Modified Organisms (GMO)

GMO's may be present in this product as a result of specific characteristics of the raw materials utilized by the raw material supplier and/or of their manufacturing process(es). Previous reviews had found that this product may contain adjuvants from PALM OIL fatty acids originating from GMO's. It does not contain JATROPHA OIL derived substances.

2.4. United States of America Standards

2.4.1. California Proposition 65: (Safe Drinking Water and Toxic Enforcement Act of 1986)

Based on available information this product does not intentionally contain any components or chemicals at levels which would be subject to Proposition 65 of the California Safe Drinking Water and Toxic Enforcement Act of 1986 and its amendments.

2.4.2. Conflict Materials: (Dodd-Frank Wall Street Reform and Consumer Protection Act)

To the best of our knowledge based upon data from our raw material supplier this product is not intentionally manufactured or formulated with the listed Conflict Materials as per Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

2.4.3. Heavy Metals: (Coalition of North-Eastern Governors - CONEG)

This product is not known to contain CONEG substances at or above the 100-ppm reporting threshold. Based on the information available from our raw material suppliers, they do not use cadmium, chromium, lead, or mercury in the manufacture or formulation of this product and do not intentionally contain any of the substances below. We do not specifically run any analysis on incoming raw materials or end products to measure for the presence of any of the substances below Meets requirements of the Model Toxics in Packaging Legislation developed in 1989 by the CONEG (Coalition of North-eastern Governors, USA).

2.4.4. US Pharmacopeia (USP) <85>

The purpose of this test is to detect and quantify the level of Bacterial Endotoxins present in an *in vitro* assay. The detection of bacterial endotoxins indicates that Gram negative bacteria are present.

The endotoxin limit set to determine compliance to USP <85> are as follows:

- For finished medical devices, ≤ 20.0 EU/device
- For medical devices in contact with cerebral fluid, ≤ 2.15 EU/device
- For intraocular ophthalmic devices, 0.2 EU/device

Additionally, to ensure the test solution is free from external influencing factors given the specific conditions of the test, a PPC recovery is completed. Results between 50% and 200% indicate that no external influences exist.

This product meets guideline requirements and as such has been certified as a USP Class VI Plastic (USP<85>, Bacterial Endotoxins Test, In Vitro). The associative PPC Recovery value was 105% and the detected endotoxin level was <0.005 EU/mL or <0.0505 EU/device.

2.4.5. US Pharmacopeia (USP) <88>

USP <88> is a series of three tests that evaluate biological reactivity of animals to polymeric material: systemic toxicity, intracutaneous reactivity and implantation.

The Systemic Injection Test and the Intracutaneous Test are designed to determine the systemic and local, respectively, biological responses of animals to plastics and other polymers by the single dose injection of specific extracts prepared from a sample. The Implantation Test is designed to evaluate the reaction of living tissue to the plastic and other polymers by the implantation of the sample itself into animal tissue.

This product meets guideline requirements and as such has been certified as a USP Class VI Plastic (USP<88>, Biological Reactivity Tests, In Vivo). Eldon James does not use additional additives or compounds when manufacturing the product.

2.4.6. US Pharmacopeia (USP) <643>

The purpose of this test is to quantify the Total Organic Carbon (TOC) content of water used for pharmaceutical applications. Organic carbon or molecules can be present in water due to the primary water source, from biofilm on water contacting surfaces, from sterile water packaging, and/or from external purification systems and components.

This product meets guideline requirements and as such has been certified as a USP Class VI Plastic (USP<643>, Total Organic Carbon (TOC) Tests). The test article measured net TOC value (0.439 ppm) was not higher than the corrected limit response value (.504 ppm).

2.4.7. US Pharmacopeia (USP) 38 & NF 33.2015 <661>

The purpose of this test is to evaluate the physical and chemical properties of each plastic housing material. The test article preparation was performed per UPS <661> standard, requiring 0.2 grams per 1 ml of extraction fluid (USP purified water). The extraction parameters where 70 ± 2 °C for 24 ± 2 hours.

This product meets guideline requirements and as such has been certified as a USP Class VI Plastic (USP<661>, Physicochemical). Tests were conducted on the material pellets, not the product itself. Eldon James does not use additional additives or compounds when manufacturing the product.

Testing is necessary to comply with USP General Chapter 32 and National Formulary 27, 2009 regulations. The procedure is described in the USP General Chapter 661.

2.4.8. US Pharmacopeia (USP) <788>

The purpose of this test is to quantify the count and size of subvisible particles in parenteral drugs. Particle sizes ≥10 µm and ≥25 µm are the focus. Testing was performed using a light-obscuration sensor.

This product meets guideline requirements and as such has been certified as a USP Class VI Plastic (USP<788>, Particulate Matter in Injections Test). The test results recorded 3 particles ≥10 µm and 0 particles ≥25 µm per twelve inches of tubing. With a tubing volume of approximately 3.02 mL, ≤1 particle/mL for particles ≥10 µm (requirement of ≤25 particles/mL) and ≤0 particles/mL for particles ≥25 µm (requirement of ≤3 particles/mL) where observed.

2.4.9. ISO 10993-5

This test is a common cytotoxicity assessment designed to assess the toxicity to cells of leachable components of the material. The material is extracted in cell culture media (Minimum Essential Medium, or “MEM”). Extracts are placed in contact with a monolayer of L-929 mouse fibroblast cells. Cells are incubated at controlled temperature and CO2 level for an additional period of time, after which they are examined microscopically for indications of cytotoxicity including malformation, degeneration, and lysis.

This product meets elusion test guideline requirements and as such has been certified as a non-cytotoxic plastic (ISO 10993-5, 1999). Tests were conducted on the material pellets, not the product itself. Eldon James does not use additional additives or compounds when manufacturing the product.

2.5. European Union Standards

2.5.1. Plant Derived Components

Based on the information provided to us by our raw material suppliers and their formulation reviews, they have found that this product does contain the following plant derivative(s):

- May contain adjuvants from PALM OIL fatty acids.
- These adjuvants may be from genetically modified organisms (GMO).
- Not JATROPHA OIL derived.

2.5.2. REACH 219 Substances (July 8th, 2021)

Based on the information provided to Eldon James from our raw material supplier and their formulation reviews, they confirm that this product does not contain SVHC Candidate List Annex XIV materials above the applicable threshold (0.1%) as updated by the European Chemical Agency as of July 8th, 2021 (219 substances).

2.5.3. RoHS

2.5.3.1 EU Directive 2015/863/EU Restriction of Hazardous Substances (RoHS 3)

Restriction on use of: lead, mercury, hexavalent chromium, polybrominated biphenyl (PBB) and polybrominated diphenyl ether (PBDE) flame retardants, at levels of greater than 0.1%; cadmium, at levels greater than 0.01%; and Pentabromodiphenylether, Octabromodiphenylether, and Decabromodiphenyl oxide, in concentrations higher than 0.1%; and HBCDD, Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), Diisobutyl phthalate (DIBP) in concentrations greater than 0.1%.

Based on the information provided by our resin supplier and their formulation reviews, they have found that the product listed above does not contain RoHS 3 substances above listed concentrations and would therefore be in compliance with substance restrictions.

2.5.3.2 EU Directive 2006/122/ Restriction of the Use of Perfluorooctanoic Acid and Perfluorooctane Sulfates (EC-RoHS)

This product does not intentionally contain perfluorinated substances.

2.5.4. Heavy Metals (ELV Directive 2000/53/EC) Coalition of Northeastern Governors (CONEG)

This product has not been checked by tests, thus the fact that these substances are to all intents and purposes absent from this product, does of course, not absolutely exclude that that toxicologically and/or regulatory irrelevant extremely low trace levels of lead, mercury, cadmium, and hexavalent chromium may unintentionally be present.

Meets requirements of the Model Toxics in Packaging Legislation developed in 1989 by the CONEG (Coalition of Northeastern Governors, USA).

2.5.5. European Directive (94/62/EC) Packaging and Packaging Waste EU Directive 2012/19/EU Waste Electrical & Electronic Equipment (WEEE)

Article 11 of European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste (last amended by Directive 2013/2/EU).

EC Directive on Waste Electrical and Electronic Equipment (WEEE) and EC Directive on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS), Recast 2011/65/EU (HBCDD, DEHP, BBP, DBP, DIBP) as amended through 2015/863/EU on 31 March 2015.

This product complies with and does not contain any of the EC Directive on Waste Electrical and Electronic Equipment (WEEE) and EC Directive on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (RoHS), Recast 2011/65/EU (HBCDD, DEHP, BBP, DBP, DIBP) as amended through 2015/863/EU on 31 March 2015.

2.5.6. European Regulation (EC) No. 1895/2005 (BADGE, BFDGE, NOGE)

This product is in compliance with European Union Commission Regulation 1895/2005/EC of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food (repeals Directive 2002/16/EC & 2004/13/EC).

2.6. Animal Derivative Content & Transmissible Spongiform Encephalitis (TSE/BSE) Risk

Based on the information provided to us by our raw material suppliers, review of their product formula and materials handling and processing procedures, this product should not contain any animal derived ingredients. Based on this information there would be no known sources of Bovine Spongiform Encephalopathy (BSE) or Transmissible spongiform encephalopathy (TSE).

3. PERFORMANCE TESTING

3.1. Sterilization

Gamma Sterilization of TPEs has been shown safe up to 45kGy. At levels up to this limit, no mechanical property changes should occur. A slight yellowing which is purely visual may become present as the radiation level approaches 45 kGy. The customer should conduct testing for any sterilization method chosen to verify performance unique to the application.

- E-beam/Gamma ≤45 kGy, no deficiencies, may color shift at higher doses.
- EtO No issues. Can safely be used.
- Autoclave Up to 135°C.

3.2. Shelf-Life

EJPrene is a TPV formulation belonging to a particular product portfolio. Other, similar chemistry formulations have been tested with respect to shelf-life for projects and products requiring FDA design history files and/or FDA submissions. Extruded tube shelf-life should be tested for each application and fluid contact but a minimum of five (5) years should be expected with aggressive, low and high pH fluids and a maximum of ten (10) years for more pH neutral fluids.

4. BPOG Extractables and Leachables

4.1. Introduction

The objective is to perform a chemical characterization of EJPrene tubing per guidance outlined in Biophorum Best Practices Guide for Extractables Testing of Polymeric Single-Use Components Used in Biopharmaceutical Manufacturing.

4.2. Test Setup

Prior to test initiation, tubing was exposed to gamma sterilization using a standard processing cycle, 25 to 50 kGy. Test articles were cut into 10cm replicate samples (S4) and 20 cm replicate samples (S3) prior to extraction. The test articles were then extracted with 10ml (S3) and 20ml (S4) of solvent at 40^{o}C for 24 hours (T1) and 21 days (T21). Extraction solvents included 50% ethanol, 0.5 N NaOH, 0.1M Phosphoric Acid (0.1 M H3PO4), and 18.2MΩ deionized water. The extractable material was then characterized using Inductively Coupled Plasma Mass Spectrometry (ICP/MS), Gas Chromatography Mass Spectrometry (GC/MS), and Liquid Chromatography Mass Spectrometry (LC/MS).

The Analytical Evaluation Threshold (AET) for the analysis was based on “Biophorum Best Practices Guide for Extractables Testing of Polymeric Single-Use Components Used in Biopharmaceutical Manufacturing” and is set at 0.1 µg/mL. The lowest standard analyzed was 1 ppm for LC and GC analysis. This was based on the “Biophorum” methodology. This resulted in the inclusion of small peaks that did not have adequate MS signal to identify the compound. All peaks above the AET were identified and assigned confidence according to the following definitions:

- **Confident:** chemical of interest is matched to compounds in a commercially available external (e.g. NIST) database
- **Tentative:** chemical of interest is matched to a custom internal database
- **Speculative:** chemical of interest does not result in a database match, but chemical formula, functional groups, compound class can be assigned

4.3. Test Results

4.3.1. GC/MS

Samples were analyzed by GC/MS using an Agilent 6890 GC with a 5973 MS and a Combi Pal headspace autosampler. Chromatographic separations were performed with a 5%-Phenyl-Arylene 95%-Dimethylpolysiloxane phase column with the dimensions 30 m x 0.25 mm x 0.25 µm. The peaks were identified or characterized using the MS detector. In addition to the samples, a mixture of reference standards was analyzed. The reference standard mixtures were utilized to establish system suitability of the instrument and estimate concentrations of organic compounds.

Table 4.3.2.1 Compounds Detected by GC/MS in 50% Ethanol Extracts

Peak No.	Compound	CAS	RT (min)	ID Level	Detection Mode	S5 (µg/cm2)		S6 (µg/cm2)	
						T1	T21	T1	T21
1	Acetic acid	64-19-7	2.918	Tentative	GC-MS	< 0.04	0.54	< 0.04	0.63
2	Benzene, 1,3-bis(1,1-dimethylethyl)-	1014-60-4	7.823	Confident	GC-MS	< 0.04	0.08	< 0.04	0.09
3	2,4-Di-tert-butylphenol	96-76-4	10.701	Confident	GC-MS	0.17	1.86	0.03	1.27
4	3,5-di-tert-Butyl-4-hydroxybenzaldehyde	1620-98-0	13.258	Confident	GC-MS	< 0.04	0.49	< 0.04	0.53
5	3,5-Cyclohexadiene-1,2-dione, 3,5- bis(1,1-dimethylethyl)-	3383-21-9	14.115	Speculative	GC-MS	< 0.04	0.08	< 0.04	0.09
6	7,9-Di-tert-butyl-1-oxaspiro(4,5)deca-6,9-diene-2,8-dione	82304-66-3	14.580	Confident	GC-MS	< 0.04	2.38	< 0.04	2.75

The structural assignments are based on parent mass internal database searching and interpretation

Table 4.3.2.2 Compounds Detected by GC/MS in 0.5 N NaOH Extracts

Peak No.	Compound	CAS	RT (min)	ID Level	Detection Mode	S5 (µg/cm2)		S6 (µg/cm2)	
						T1	T21	T1	T21
1	3,5-di-tert-Butyl-4-hydroxybenzaldehyde	1620-98-0	13.273	Confident	GC-MS	0.06	0.91	< 0.04	< 0.04

The structural assignments are based on parent mass internal database searching and interpretation

Table 4.3.2.3 Compounds Detected by LC/UV/ESI-MS in 0.1 M H3PO4 Extracts

Peak No.	Compound	CAS	RT (min)	ID Level	Detection Mode	S5 (µg/cm2)		S6 (µg/cm2)	
						T1	T21	T1	T21
1	Cyclic octaatomic sulfur	10544-50-0	15.766	Confident	GC-MS	< 0.04	0.07	< 0.04	< 0.04

The structural assignments are based on parent mass internal database searching and interpretation

Table 4.3.2.4 Compounds Detected by GC/MS in Water Extracts

Peak No.	Compound	CAS	RT (min)	ID Level	Detection Mode	S5 (µg/cm2)		S6 (µg/cm2)	
						T1	T21	T1	T21
1	Benzyl alcohol	100-51-6	5.555	Confirmed	GC-MS	< 0.04	0.05	< 0.04	NA
2	Unknown (Possibly PEG related)	NA	12.071	Speculative	GC-MS	< 0.04	< 0.04	< 0.04	NA
3	Unknown (Response to Low)	NA	13.770	Unknown	GC-MS	0.12	< 0.04	< 0.04	NA
4	Unknown (Likely Siloxane Related)	NA	13.979	Speculative	GC-MS	0.05	< 0.04	< 0.04	NA
5	Unknown (Response to Low)	NA	14.123	Unknown	GC-MS	0.05	< 0.04	< 0.04	NA
6	Unknown (Response to Low)	NA	14.452	Unknown	GC-MS	0.06	< 0.04	< 0.04	NA
7	Unknown (Response to Low)	NA	26.756	Unknown	GC-MS	< 0.04	< 0.04	< 0.04	NA

The structural assignments are based on parent mass internal database searching and interpretation

4.3.2. Heated Head Space GC/MC (HHS-GC/MS)

Samples were analyzed by GC/MS using an Agilent 6890 GC with a 5973 MS and a Combi Pal headspace autosampler. Chromatographic separations were performed with a 6%-cyanopropyl phenyl-94% Dimethylpolysiloxane phase column 60 m x 0.25 mm x 1.4 µm. The peaks were identified or characterized using the MS. The reference standard mixtures were utilized to establish system suitability of the instrument and estimate concentrations of organic compounds.

The overall results indicate that the ethanol was a result of atmospheric uptake. Ethanol was used as an extraction solvent. During the preparation and incubation time, the extraction solution could absorb the ethanol from the atmosphere in the lab or environmental chamber.

Table 4.3.2.1 Compounds Detected by HHS-GC/MS in 0.5 N NaOH Extracts

Peak No.	Compound	CAS	RT (min)	ID Level	Detection Mode	S5 (µg/cm2)		S6 (µg/cm2)	
						T1	T21	T1	T21
1	Ethanol	64-17-5	5.823	Confident	HS-GCMS	< 0.04	0.30	< 0.04	0.31
2	IPA	67-63-0	6.378	Confident	HS-GCMS	< 0.04	0.22	< 0.04	0.22
3	Acetone	67-64-1	6.445	Confident	HS-GCMS	< 0.04	0.23	< 0.04	0.23
4	2-Butanone, 3,3-dimethyl-	75-97-8	10.841	Tentative	HS-GCMS	< 0.04	0.45	< 0.04	0.45

The structural assignments are based on parent mass internal database searching and interpretation

Table 4.3.2.2 Compounds Detected by HHS-GC/MS in 0.1 M H_3PO_4 Extracts

Peak No.	Compound	CAS	RT (min)	ID Level	Detection Mode	S5 (µg/cm2)		S6 (µg/cm2)	
						T1	T21	T1	T21
1	Ethanol	64-17-5	5.81	Confident	HS-GCMS	< 0.04	0.57	< 0.04	0.57

The structural assignments are based on parent mass internal database searching and interpretation

Table 4.3.2.3 Compounds Detected by HHS-GC/MS in Water Extracts

Peak No.	Compound	CAS	RT (min)	ID Level	Detection Mode	S5 (µg/cm2)		S6 (µg/cm2)	
						T1	T21	T1	T21
1	Ethanol	64-17-5	5.81	Confident	HS-GCMS	< 0.04	0.29	< 0.04	0.57

The structural assignments are based on parent mass internal database searching and interpretation

4.3.3. LC/MS

The instrument analysis was completed via UPLC/MS using either Vanquish stack or Dionex Ultimate 3000 stack, which consists of a degasser, a dual solvent pump, an autosampler, a column compartment, and a diode array detector. The instrument flow is then directed to either a Thermo Fisher IQ-X mass spectrometer (ESI) or Thermo Finnigan Q Exactive (APCI). Chromatographic separation was accomplished using a C8 column and gradient method with water and acetonitrile containing ammonium acetate. Mass spectrometer scans were performed in a data dependent mass spectrum mode over the full range of the instrument in both polarities to maximize coverage. The samples were analyzed using ESI and APCI sources. The structural assignments are based on parent mass internal database searching and interpretation.

In addition to the samples, a mixture of reference standards was analyzed to estimate concentration of analytes and to establish system suitability of the instrument. System suitability, linearity, and LOQ/LOD were evaluated using the bisphenol A in the mix. The results are presented in Table. Semi-quantitative analysis was performed using bisphenol A.

Table 4.3.3.1 Compounds Detected by LC/UV/ESI and APCI-MS in 50% Ethanol Extracts

Peak No.	Compound	CAS	RT (min)	ID Level	Detection Mode	S5 (µg/cm2)		S6 (µg/cm2)	
						T1	T21	T1	T21
1	C10H16O5	N/A	4.05	Speculative	ESI+	<0.02	0.11	<0.02	0.15
2	C17H26O5 - Likely structurally related to co-eluting C17H26O4 - Likely contains phenyl group	N/A	4.89	Speculative	UV	0.17	0.27	0.20	0.30
3	C17H26O4 - Likely structurally related to co-eluting C17H26O5 (loss of OH) - Likely contains phenyl group	N/A	4.94	Speculative	ESI-	<0.02	0.18	<0.02	0.23
4	(9Z)-12-Oxo-9-dodecenoic acid	60485-39-4	6.66	Confident	ESI-	<0.02	0.13	<0.02	0.12
5	Bis[2,4-bis(2-methyl-2-propanyl)phenyl] hydrogen phosphate	69284-93-1	7.13	Tentative	UV	0.46	0.91	0.43	0.99
6	3,5-di-tert-butyl-4-hydroxybenzaldehyde	1620-98-0	7.88	Confident	UV	0.42	0.95	0.63	0.96
7	2,4-di-tert-Butylphenol	96-76-4	8.40	Confident	UV	0.44	1.22	0.38	1.15
8	Palmitic Acid	57-10-3	8.55	Confident	ESI-	0.41	0.20	0.38	0.23
9	C21H44O5	N/A	8.67	Speculative	ESI+	<0.02	0.22	<0.02	0.24

10	C24H41NO2 - Possibly structurally similar to Erucamide	N/A	8.88	Speculative	ESI+	<0.02	0.14	<0.02	0.14
11	1-(4-Morpholinyl)-9-octadecen-1-one	5299-52-5	9.04	Confident	ESI+	<0.02	0.11	<0.02	0.12
12	C10H16O5	N/A	4.05	Speculative	ESI+	<0.02	0.11	<0.02	0.15

The structural assignments are based on parent mass internal database searching and interpretation

Table 4.3.3.2 Compounds Detected by LC/UV/ESI-MS in 0.5 N NaOH Extracts

Peak No.	Compound	CAS	RT (min)	ID Level	Detection Mode	S5 (µg/cm2)		S6 (µg/cm2)	
						T1	T21	T1	T21
1	Dibutyl itaconate	2155-60-4	4.86	Tentative	ESI-	<0.02	0.54	<0.02	0.48
2	3,5-di-tert-butyl-4-hydroxybenzaldehyde	1620-98-0	7.87	Confident	UV	0.42	1.60	0.27	1.35
3	C40H51O2P	N/A	10.76	Speculative	ESI-	<0.02	0.09	<0.02	<0.02

The structural assignments are based on parent mass internal database searching and interpretation

Table 4.3.3.3 Compounds Detected by LC/UV/ESI-MS in 0.1 M H_3PO_4 Extracts

Peak No.	Compound	CAS	RT (min)	ID Level	Detection Mode	S5 (µg/cm2)		S6 (µg/cm2)	
						T1	T21	T1	T21
No Peaks Above Reporting Limit									

The structural assignments are based on parent mass internal database searching and interpretation

Table 4.3.3.4 Compounds Detected by LC/UV/ESI-MS in Water Extracts

Peak No.	Compound	CAS	RT (min)	ID Level	Detection Mode	S5 (µg/cm2)		S6 (µg/cm2)	
						T1	T21	T1	T21
No Peaks Above Reporting Limit									

The structural assignments are based on parent mass internal database searching and interpretation

4.3.4. ICP/MS

Aliquots of water, 0.1 M H3PO4, and 0.5 N NaOH extracts were submitted for ICP/MS analysis. The limit of detection (LOD) for the ICPMS method was reported for each extracted element. Additionally, the reported concentrations of the sample extracts were corrected for the amount observed in the controls. If the element is not detected in the solution, then a "<LOD" is reported. If the concentration is less than the concentration in the control, the reported value is "- ". A multicomponent check solution was also analyzed to verify recoveries. The percent recovery of the standards ranged from 90 - 100%. Silicon and Boron were observed in the "0.5N NaOH T=1 day" samples. The results indicate that this is likely from borosilicate glassware used (tube plugs and vials) and not the tubing. There were no significant amounts of PDMS (or other Si containing) material in the GC and LC analysis that would account for the amount of Si detected by ICP/MS. This indicates that the silicon source is not related to the tubing.

Table 4.3.4.1 ICP/MS Results for 0.5 N NaOH Extracts

Element	*LOD (µg/L)*	T=1 Day					T=21 Day				
		Control (µg/mL)	Result Lot 1 (µg/mL)	Result Lot 2 (µg/mL)	Result Lot 1 (µg/cm2)	Result Lot 2 (µg/cm2)	Control (µg/mL)	Result Lot 1 (µg/mL)	Result Lot 2 (µg/mL)	Result Lot 1 (µg/cm2)	Result Lot 2 (µg/cm2)
Li	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	0.2	<LOD	<LOD	<LOD	<LOD
Be	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
B	1	12.0	7.0	4.0	2.7	1.5	24	16.00	24.00	6.11	9.17
Na	1	Matrix	n.a.	n.a.	n.a.	n.a.	Matrix	Matrix	Matrix	Matrix	Matrix
Mg	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Al	0.1	5.4	v	0.2	-	-	27	-	-	-	-
Si	0.5	91.0	49.0	59.0	18.7	22.5	260	50.00	140.00	19.11	53.50
P	1	< 1	<LOD	<LOD	<LOD	<LOD	< 1	<LOD	<LOD	<LOD	<LOD
K	0.1	2	-	-	-	-	18	-	-	-	-
Ca	0.1	< 1	<LOD	<LOD	<LOD	<LOD	< 1	<LOD	<LOD	<LOD	<LOD
Sc	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Ti	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
V	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Cr	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Mn	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Fe	1	< 1	<LOD	<LOD	<LOD	<LOD	< 1	<LOD	<LOD	<LOD	<LOD
Co	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Ni	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	0.2	<LOD	<LOD	<LOD	<LOD
Cu	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Zn	0.1	< 0.1	0.40	0.50	0.06	0.16	< 0.1	0.70	0.70	<LOD	<LOD
Ga	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Ge	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
As	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Se	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Rb	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	0.1	<LOD	<LOD	<LOD	<LOD
Sr	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Y	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Zr	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Nb	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Mo	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Ru	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Rh	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Pd	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Ag	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Cd	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
In	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Sn	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Sb	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Te	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Cs	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Ba	0.01	1.1	-	-	-	-	14	-	-	-	-
La	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Ce	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Pr	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD

Nd	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Sm	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Eu	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Gd	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Tb	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Dy	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Ho	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Er	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Tm	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Yb	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Lu	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Hf	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Ta	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
W	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Re	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Os	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Ir	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Pt	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Au	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Hg	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Tl	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Pb	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Bi	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Th	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
U	0.1	< 0.1	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD

Table 4.3.4.2 ICP/MS Results for 0.1 M H_3PO_4 Extracts

Element	*LOD (µg/L)*	T=1 Day					T=21 Day				
		Control (µg/mL)	Result Lot 1 (µg/mL)	Result Lot 2 (µg/mL)	Result Lot 1 (µg/cm2)	Result Lot 2 (µg/cm2)	Control (µg/mL)	Result Lot 1 (µg/mL)	Result Lot 2 (µg/mL)	Result Lot 1 (µg/cm2)	Result Lot 2 (µg/cm2)
Li	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Be	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
B	1	4.6	2.6	1.2	1.0	0.5	6.9	0.30	0.70	-	-
Na	1	9.0	2.0	-	0.8	-	13	-	-	-	-
Mg	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	0.10	<LOD	0.032
Al	0.1	0.7	-	-	-	-	1.4	-	-	-	-
Si	0.5	<LOD	<LOD	<LOD	<LOD	<LOD	< 5	<LOD	<LOD	<LOD	<LOD
P	1	Matrix	n.a	n.a	n.a	n.a	Matrix	Matrix	Matrix	Matrix	Matrix
K	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 1	<LOD	<LOD	<LOD	<LOD
Ca	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 1	<LOD	<LOD	<LOD	<LOD
Sc	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Ti	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
V	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Cr	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Mn	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Fe	1	<LOD	<LOD	<LOD	<LOD	<LOD	< 1	<LOD	<LOD	<LOD	<LOD
Co	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Ni	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD

Cu	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Zn	0.1	<LOD	0.10	<LOD	<LOD	<LOD	0.2	0.90	1.80	0.34	0.69
Ga	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Ge	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
As	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Se	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Rb	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Sr	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Y	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Zr	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Nb	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Mo	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Ru	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Rh	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Pd	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Ag	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Cd	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
In	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Sn	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Sb	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Te	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Cs	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Ba	0.01	0.40	-	-	-	-	0.6	-	-	-	-
La	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Ce	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Pr	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Nd	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Sm	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Eu	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Gd	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Tb	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Dy	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Ho	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Er	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Tm	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Yb	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Lu	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Hf	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Ta	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
W	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Re	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Os	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Ir	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Pt	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Au	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Hg	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Tl	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Pb	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Bi	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Th	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
U	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD

Table 4.3.4.3 ICP/MS Results for Water Extracts

Element	*LOD (µg/L)*	T=1 Day					T=21 Day				
		Control (µg/mL)	Result Lot 1 (µg/mL)	Result Lot 2 (µg/mL)	Result Lot 1 (µg/cm2)	Result Lot 2 (µg/cm2)	Control (µg/mL)	Result Lot 1 (µg/mL)	Result Lot 2 (µg/mL)	Result Lot 1 (µg/cm2)	Result Lot 2 (µg/cm2)
Li	0.01	<LOD	0.01	<LOD	0.004	<LOD	0.01	<LOD	<LOD	<LOD	<LOD
Be	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
B	0.1	4.3	2.70	-	1.0	-	5.0	-	-	-	-
Na	0.1	6.8	3.20	-	1.2	-	8.5	-	-	-	-
Mg	0.01	<LOD	< 0.01	0.01	<LOD	<LOD	< 0.01	0.02	0.02	0.01	0.01
Al	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Si	0.5	5.4	2.70	-	1.03	-	7.8	1.40	-2.10	0.54	-
P	0.1	1.3	-	-	-	-	0.3	<LOD	<LOD	<LOD	<LOD
K	0.1	0.1	<LOD	<LOD	<LOD	<LOD	0.1	0.10	0.10	0.04	0.04
Ca	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Sc	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Ti	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
V	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Cr	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Mn	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Fe	0.1	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.1	<LOD	<LOD	<LOD	<LOD
Co	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Ni	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Cu	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Zn	0.1	0.07	0.06	0.16	0.023	0.061	< 0.01	<LOD	<LOD	<LOD	<LOD
Ga	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Ge	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
As	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Se	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Rb	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Sr	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Y	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Zr	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Nb	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Mo	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Ru	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Rh	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Pd	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Ag	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Cd	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
In	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Sn	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Sb	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Te	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Cs	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Ba	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	0.04	0.05	0.015	0.019
La	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Ce	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Pr	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD

Nd	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Sm	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Eu	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Gd	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Tb	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Dy	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Ho	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Er	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Tm	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Yb	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Lu	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Hf	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Ta	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
W	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Re	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Os	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Ir	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Pt	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Au	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Hg	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Tl	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Pb	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Bi	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
Th	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD
U	0.01	<LOD	<LOD	<LOD	<LOD	<LOD	< 0.01	<LOD	<LOD	<LOD	<LOD

Table 4.3.4.4 ICP/MS Overall Results

Element		ICH Q3D Class	Highest result of all lots tested (µg/cm²) (1 or 21 days)		
			Water	0.1 M H_3PO_4	0.5 N NaOH
Lithium	Li	3	0.004	<LOD	<LOD
Barium	Ba	3	0.019	-	-
Potassium	K	N/A	0.038	<LOD	-
Zinc	Zn	N/A	0.06	0.69	0.16
Silicon	Si	N/A	1.03	<LOD	53.50
Boron	B	N/A	1.03	0.99	9.17
Sodium	Na	N/A	1.22	0.76	N/A
Magnesium	Mg	N/A	<LOD	0.03	<LOD