

Title:

## Verasonics Vendor Restricted Materials Policy

Document Purpose:

This document communicates the minimum environmental requirements for products supplied by suppliers to Verasonics, Inc.

Legal Notice:

*THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION WHICH IS PROPRIETARY TO VERASONICS. NEITHER THE DOCUMENT NOR THE INFORMATION CONTAINED THEREIN SHOULD BE DISCLOSED OR REPRODUCED IN WHOLE OR IN PART, WITHOUT EXPRESS WRITTEN CONSENT OF VERASONICS Inc*

Owner:

Charles Ward

Verasonics Approval:

Name: Charles Ward

Signature:  Date: 7/14/2020

Affected Person(s):

All Verasonics Product Suppliers, Engineering, and Procurement.

Address:

Verasonics, Inc.  
11335 NE 122nd Way  
Suite 100  
Kirkland, WA 98034

# Verasonics Confidential

## Table of Contents

<b>1</b>	<b>Overview.....</b>	<b>3</b>
1.1	Purpose.....	3
1.2	Scope.....	3
1.3	References to Applicable Regulations, Directives & Standards.....	3
1.4	Change History.....	3
1.5	Definitions.....	4
1.6	Responsibilities.....	5
<b>2</b>	<b>Product Environmental Compliance Requirements and Procedure.....</b>	<b>6</b>
2.1	Supplier Requirements.....	6
<b>3</b>	<b>Records.....</b>	<b>8</b>

## 1 Overview

### 1.1 Purpose

This document communicates the minimum environmental requirements for products supplied by suppliers to Verasonics, Inc.

### 1.2 Scope

Define responsibility of suppliers in meeting regulatory environmental compliance globally. Define the documentation required of suppliers claiming compliance to identified environmental legislation.

### 1.3 References to Applicable Regulations, Directives & Standards

Ref	Document Title
[1]	EU RoHS: 2011/65/EU and its amendments/subsequent versions/annexures including EU Directive 2015/863.
[2]	EU REACH: 1907/2006/EC and its amendments/subsequent versions/annexures.
[3]	California Prop 65
[4]	Standards as called out in Appendix A

### 1.4 Change History

Date	Section(s)	Description
Apr 13 <sup>th</sup> , 2020	All	Document created

## 1.5 Definitions

Term	Document Title
RM	Restricted Materials. Restricted Materials regulatory requirements include all the regulations listed previously in section 1.3.
RoHS	Restriction of Hazardous Substances. Widely implied restriction by EU RoHS as max concentration of 1000ppm for Pb, Hg, Cr6+, PBB and PBDE, and 100ppm for Cd in homogenous material. Expanded in EU 2015/863 to include four phthalates (DEHP, BBP, DBP, & DIBP) 1000ppm [1].
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals [2].
SVHC	Substance of Very High Concern. Chemicals identified on European Chemical's agency's (ECHA) website that have REACH compliance requirements.
Verasonics Suppliers or Supply Chain	Entities including, but not limited to: Contract Manufacturer, Original Equipment Manufacturer, Original Design Manufacturer, Joint Design Manufacturer, Supplier, or Vendor.
CoC	A Certificate of Compliance that states the standard/regulation and version to which the certificate applies.
Simple Article	A Simple Article is an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition. A Simple Article does not cease to be a Simple Article when it is assembled or joined with other objects in order to form with them a complex product.
Homogeneous Material	Any material that cannot be mechanically disjointed into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding or scraping.
Prop 65	Proposition 65 protects the state's drinking water sources from being contaminated with chemicals known to cause cancer, birth defects or other reproductive harm, and requires businesses to inform Californians about exposures to such chemicals.  Proposition 65 requires the state to maintain and update a list of chemicals known to the state to cause cancer or reproductive toxicity.

**Table 1**

## 1.6 Responsibilities

Role	Responsibility
Verasonics	<p>Develop product designs that can be built to comply with RM regulatory requirements.</p> <p>Where Verasonics' engineering specifies a component with a specific manufacturer's SKU, it is Verasonics engineering's responsibility to ensure that the selected part meets RM requirements.</p>
	Ensure that Verasonics Supply Chain entities have been provided this information and responded with the appropriate certification(s) and documentation.
	Maintain and update this procedure. Provide guidance on any specification relation questions from suppliers.
	Audit suppliers as required.
Verasonics Supplier	<p>Develop a thorough understanding of RoHS and other RM regulations and maintain comprehensive and effective systems to ensure compliance to these RM requirements. Carry out selective analysis of high-risk components/materials/vendors.</p>
	<p>Review this specification document and certify compliance with the EU RoHS Directive and provide the appropriate EU REACH &amp; Prop 65 documentation for materials/parts supplied to or on behalf of Verasonics, Inc.</p> <p>The certifications and documentation should be reviewed and updated at least annually, or more often if standards change.</p> <p>Verasonics reserves the right to request additional information, including test reports, depending on the risk rating of the materials provided and Verasonics' experience rating for supplier.</p>
	Validate that material purchased for use in product delivered to Verasonics is compliant. Collect and maintain records demonstrating compliance with this policy.
	Ensure that these RM requirements are maintained throughout supplier's supply chain.
	Promptly notify Verasonics of any actual breaches to this RM policy.
	Promptly notify Verasonics of any deficiencies in the design or documentation provided by Verasonics that might lead to a breach of this RM policy or the underlying regulations.

**Table 2**

## 2 Product Environmental Compliance Requirements and Procedure

Verasonics is committed to complying with legislative mandates to ban or limit the quantities of hazardous material in electronic products and to meet the growing requirements from our customers to supply environmentally friendly products. As a result, we have developed the following procedure for our suppliers and supply chain partners.

### 2.1 Supplier Requirements

1. Develop and maintain Restricted Materials policies and procedures which include the following:
  - 1.1. Understand regulatory requirements related to RM and develop appropriate policies and procedures.
  - 1.2. Employees and contractors should be trained on RM policies and procedures.
  - 1.3. RM policies and procedures shall be enforced throughout the supply chain and vendors should be audited as required.
  - 1.4. Copies of the supplier's procedures shall be provided to Verasonics as requested.
2. Notify Verasonics by individual part number of its EU RoHS compliance level, including any specific exemptions claimed. \*
  - 2.1. Initial compliance notification shall be via a CoC.
  - 2.2. Annually, or more often as standards change, supplier shall recertify all qualified Verasonics products as being compliant with EU RoHS.
3. Notify Verasonics, by individual part number, if a part contains EU REACH SVHC and chemicals on the California Prop 65 list. \*
  - 3.1. Initial builds shall include a notification of all SVHC's in excess of 0.1% weight in a simple item, specifying the SVHC's in excess of 0.1% and the location of the SVHC in excess of 0.1%, and the presence of chemicals on the California Prop 65 list.
  - 3.2. As the SVHC list changes, the supplier shall update and submit the notification with consideration to the modified listing of SVHCs.
  - 3.3. As the Prop 65 List changes, the supplier shall update and submit the notification with consideration to the modified California Prop 65 list.
  - 3.4. Suppliers shall provide Verasonics with part number attribute data including, but not limited to, HAZMAT, EU REACH SVHC, and California Prop 65 listed chemical content by percent by weight (%).
  - 3.5. In order to reduce the reporting handling burden on our suppliers, we recommend a single REACH/Prop 65/HAZMAT report containing a listing of all SVHC's >0.1%, all HAZMAT items, and all items on the current Prop 65 List by Part Number supplied to Verasonics

# Verasonics Confidential

**\* Note that Verasonics is responsible for those components where a specific manufacturer's part number is specified in the design document file. Supplier is responsible for all items where supplier or supplier's supply chain selects the components, materials, or manufacturer.**

4. When a part or product with identical form, fit, and function exists in both RoHS compliant and RoHS non-compliant versions, the supplier shall assign different part numbers to the two versions.
5. Suppliers shall segregate RoHS compliant product from non-RoHS compliant product and ensure no intermingling of RoHS conforming product with non-conforming product.
6. Upon infringement of any legislation/regulation, the supplier shall notify Verasonics of the following within, at minimum, 24 hours of identifying the infringement:
  - Nature of infringement.
  - Extent of infringement.
  - Product affected, lots, serial numbers, etc.
  - Suggested course of action.
  - Planned corrective action.
  - Plan to provide exchange of defective material including installed base.
7. Suppliers shall notify Verasonics on becoming aware of upcoming legislation changes and any consequential change in parts/product/reporting.
8. Supplier shall notify Verasonics in the event supplier becomes aware of any deficiencies in the design provided by Verasonics or in the design documentation provided by Verasonics that might lead to a non-compliant product.
9. PCNs: Supplier shall notify Verasonics in advance of any proposed changes, including changes to processes, that might change form, fit, function or the material composition of the items/parts supplied to Verasonics.

## **3 Records**

Supplier shall keep copies of all documentation and information related to this procedure, whether created by supplier or collected from supplier's supply chain. This information should be retained by Supplier for ten (10) years and made available to Verasonics upon request.



## Appendix A

### Applicable Standards

IEC/TR 62476:2010	Guidance for the evaluation of products with respect to substance-use restrictions in electrical and electronic products
IEC 63000:2016	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
IEC 62321:2008	Electrotechnical products - Determination of levels of six regulated substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers)
IEC 62321-1:2013	Determination of certain substances in electrotechnical products - Part 1: Introduction and overview
IEC 62321-2:2013	Determination of certain substances in electrotechnical products - Part 2: Disassembly, disjointment and mechanical sample preparation
IEC 62321-3-1:2013	Determination of certain substances in electrotechnical products - Part 3-1: Screening - Lead, mercury, cadmium, total chromium and total bromin by X-ray fluorescence spectrometry
IEC 62321-3-2:2013	Determination of certain substances in electrotechnical products - Part 3-2: Screening - Total bromine in polymers and electronics by Combustion - Ion Chromatography
IEC 62321-4:2017	Determination of certain substances in electrotechnical products - Part 4: Mercury in polymers, metals and electronics by CV-AAS, CV-AFS, ICP-OES and ICP-MS
IEC 62321-5:2013	Determination of certain substances in electrotechnical products - Part 5: Cadmium, lead and chromium in polymers and electronics and cadmium and lead in metals by AAS, AFS, ICP-OES and ICP-MS
IEC 62321-6:2015	Determination of certain substances in electrotechnical products - Part 6: Polybrominated biphenyls and polybrominated diphenyl ethers in polymers by gas chromatography - mass spectrometry (GC-MS)
IEC 62321-7-1:2015	Determination of certain substances in electrotechnical products - Part 7-1: Hexavalent chromium - Presence of hexavalent chromium (Cr (VI)) in colourless and coloured corrosion-protected coatings on metals by the colorimetric method

# Verasonics Confidential

IEC 62321-7-2:2017	Determination of certain substances in electrotechnical products - Part 7-2: Hexavalent chromium - Determination of hexavalent chromium (Cr (VI)) in polymers and electronics by the colorimetric method
IEC 62321-8:2017	Determination of certain substance in electrotechnical products - Part 8: Phthalates in polymers by gas chromatography-mass spectrometry (GC-MS), gas chromatography-mass spectrometry using a pyrolyzer/thermal desorption accessory (Py/TD-GC-MS)
IEC 62474:2012	Material declaration for products of and for the electrotechnical industry
IEC TR 62474-1:2015	Material declaration for products of and for the electrotechnical industry - Part 1: Guidance for the implementation of IEC 62474

**End of Document**