

# Sea-Bird Scientific Restricted Materials Supplier Specification

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Revision: A

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## 1. SCOPE

This document defines the restricted materials requirements for suppliers of parts and materials integrated or otherwise incorporated into Sea-Bird Scientific products. The restrictions include material restrictions, material declaration requirements, and supplier communication requirements.

Compliance with this document is required for Sea-Bird Scientific's suppliers. Failure to comply could lead to significant compliance and business issues for Sea-Bird Scientific.

All of the requirements listed below are based on specific global regulatory requirements. Components and materials intended for medical devices have additional requirements that are listed at the end of each section.

## 2. ASSOCIATED DOCUMENTS / LEGISLATION

Legislation	Description
DIRECTIVE 2002/95/EC	ROHS DIRECTIVE
DIRECTIVE 2011/65/EU	ROHS DIRECTIVE RECAST
REGULATION 765/2008	REQUIREMENTS FOR CE MARKING
DECISION 768/2008	CE CONFORMITY ASSESSMENT
REGULATION 1907/2006	REACH REGULATION
REGULATION 276/2010	ORGANOSTANNIC AMENDMENT TO REACH
STANDARD SJ/T 11363-2006	MATERIALS RESTRICTIONS - CHINA ROHS
STANDARD SJ/T 11364-2006	MARKING - CHINA ROHS

CALIFORNIA PROPOSITION 65	SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT
CALIFORNIA PERCHLORATE	BEST MANAGEMENT PRACTICES FOR PERCHLORATE
IMERC	US STATE REGULATIONS ON MERCURY IN PRODUCTS
21CFR801.437	USER LABELING FOR DEVICES CONTAINING LATEX
MONTREAL PROTOCOL	SUBSTANCES THAT DEplete THE OZONE LAYER
SECTION 1502 OF DODD-FRANK	CONFLICT MINERALS
2012/0266 (COD)	PROPOSED EU MEDICAL DEVICE REGULATION
EN 50581:2012	EU STANDARD FOR ROHS RECAST TECHNICAL FILE
DIRECTIVE 93/42/EEC	MEDICAL DEVICE DIRECTIVE (MDD)
FRENCH BPA IN FOOD LAW	DEHP AND BPA RESTRICTIONS IN MEDICAL PRODUCTS
HEALTH CANADA 08-111801-312	HEALTH CANADA DEHP AND BPA NOTIFICATION
3A	US - DAIRY

### 3. RESTRICTIONS

#### 3.1 RoHS

- 1) Parts and materials provided to Sea-Bird Scientific shall comply with the materials restrictions of Article 4 of the RoHS Directive recast (2011/65/EU).
- 2) No substances above the levels described in Annex II of RoHS recast will be permitted in homogeneous materials with the following exceptions:
  - a. The part or material benefits from an active and valid exemption listed in either Annex III or Annex IV (if applicable) of RoHS recast.
  - b. The part or material falls into one of the categories below and is out of scope of the RoHS recast material restrictions requirements.

Part Type	Reason out of scope
BATTERIES	BATTERIES AND BATTERY PACKS ARE NOT COVERED BY ROHS
PRODUCT PACKAGING DISCARDED BY THE USER	NOT INTENDED TO STAY WITH THE PRODUCT FOR ITS ENTIRE LIFETIME
CONSUMABLES	NOT INTENDED TO STAY WITH THE PRODUCT FOR ITS ENTIRE LIFETIME
PRODUCT DOCUMENTATION	NOT INTENDED TO BE DISPOSED OF IN THE SAME WASTE STREAM AS THE EEE
SOFTWARE	NOT A PHYSICAL PART OR MATERIAL OF THE FINAL PRODUCT

### 3.2 Dibutyl Tin

- 1) Parts and materials provided to Sea-Bird Scientific shall comply with the dibutyl tin restrictions of Regulation 276/2010 amending the REACH Regulation 1907/2006.
- 2) Dibutyl tin above 1,000 ppm of tin is not allowed in homogenous parts and materials provided to Sea-Bird Scientific.

### 3.3 Ozone Depleting Substances

- 1) Parts and materials provided to Sea-Bird Scientific shall comply with the requirements of the Montreal Protocol.
- 2) Parts and materials provided to Sea-Bird Scientific cannot contain or be manufactured with ozone depleting substances.

### 3.4 Conflict Minerals

- 1) Tin, tantalum, tungsten, and gold (3TGs) in parts and materials provided to Sea-Bird Scientific are required to be conflict free by 1 January 2015.
- 2) In advance of 1 January 2015, Sea-Bird Scientific's suppliers are required to be working towards becoming conflict free and sourcing only from smelters certified by the conflict free smelter (CFS) program.
- 3) See the conflict minerals sections of the materials declaration / certification section of this document for more information.

### 3.5 Latex

- 1) Only for parts and components intended for Medical Devices.
- 2) Parts and materials provided to Sea-Bird Scientific shall comply with the latex restrictions of 21CFR801.437.
- 3) No natural rubber latex is permitted in parts and materials provided to Sea-Bird Scientific.

### 3.6 Tubes

- 1) Only for parts and components intended for Medical Devices.
- 2) Parts and materials provided to Sea-Bird Scientific shall comply with the requirements of the French BPA in food legislation.
- 3) No tubes provided to Sea-Bird Scientific may contain over 1,000 ppm DEHP unless otherwise approved by Sea-Bird Scientific.

## 4. MATERIAL DECLARATION / CERTIFICATION

### 4.1 RoHS

- 1) Suppliers of parts shall provide a certificate of compliance, material declaration, or test report for RoHS and valid information on any RoHS exemptions used.
- 2) The certificate of compliance, material declaration, or test report must conform to the requirements of EN 50581:2012.
- 3) Valid certificates of compliance, material declarations, or test reports can take the form of any of the following:

Declaration Type	Declaration by	Acceptable Documents
SUPPLIER DECLARATION	MANUFACTURER, DISTRIBUTOR, OR SUPPLIER	CERTIFICATE OF COMPLIANCE
MATERIAL DECLARATION	MANUFACTURER OR SUPPLIER DECLARATION	MANUFACTURER MATERIAL DECLARATION TO EN 62474:2012 OR EQUIVALENT
TEST REPORT	ANY	TEST REPORT TO EN OR IEC 62321

- 4) A certificate of compliance, materials declaration, or test report shall:
  - a. Include the part or material in question
  - b. Include the name of the declaring company, preferably with a signature
  - c. Clearly indicate compliance to RoHS
  - d. Identify the use of any valid exemptions
  - e. Be properly reviewed and correct to the best of the supplier's knowledge.

#### **4.2 REACH Substances of Very High Concern (SVHC)**

- 1) Upon request, suppliers of parts shall provide information on whether any of the parts or materials they supply to Sea-Bird Scientific contains any SVHCs above 0.1% w/w.
- 2) Further details are provided in the communication requirements section of this document.

#### **4.3 Conflict Minerals**

- 1) Upon request, suppliers of parts shall provide information regarding the country of origin and conflict free nature of the tin, tantalum, tungsten, or gold (3TGs) in their product.
- 2) The information must be provided in a valid EICC-GeSI reporting template.
- 3) Suppliers whose parts and products do not contain 3TGs are excluded from the extended reporting requirements if they provide an EICC-GeSI reporting template with the lack of 3TGs in their parts and materials clearly identified.

#### **4.4 China RoHS**

- 1) Upon request, suppliers of parts shall provide restricted materials information required under China RoHS.
- 2) The requested information could include
  - a. Environmental friendly use period and labeling (in years)
  - b. Hazardous Substance Disclosure Table.

#### **4.5 EU Medical Device Directive and Health Canada.**

- 1) Only for parts and components intended for Medical Devices.
- 2) Upon request, suppliers of parts shall provide information as to whether their parts contain any phthalates restricted by the EU medical device directive and whether their parts contain any materials derived from bisphenol-A (BPA).

## **5. COMMUNICATION REQUIREMENTS**

### **5.1 REACH Substances of Very High Concern (SVHC)**

- 1) Suppliers to Sea-Bird Scientific are required to inform Sea-Bird Scientific if any of the parts and materials contains any REACH SVHCs above 0.1% w/w.
- 2) Suppliers to Sea-Bird Scientific are expected to keep up to date on new additions to the REACH SVHC list and inform Sea-Bird Scientific promptly if there is a change in a part or material REACH SVHC declaration.

### **5.2 California Proposition 65**

- 1) Suppliers to Sea-Bird Scientific are required to inform Sea-Bird Scientific if any of the parts and materials supplied to Sea-Bird Scientific contains a California Proposition 65 listed substance and the quantity or concentration of the listed substance in the part or material.
- 2) Suppliers to Sea-Bird Scientific are required to inform Sea-Bird Scientific if any of the parts and materials supplied to Sea-Bird Scientific contains any plastics having Pb in excess of 300 ppm.

### **5.3 Mercury**

Suppliers to Sea-Bird Scientific are required to inform Sea-Bird Scientific if any of the parts and materials supplied to Sea-Bird Scientific contains any intentionally added mercury or mercury compound, the amount or concentration of the intentionally added mercury or mercury compound, and the location of the mercury or mercury compound in the part or material. Additionally, suppliers are required to inform Sea-Bird Scientific if any of the parts and materials supplied to Sea-Bird Scientific contain Hg above 0.1% w/w that is not intentionally added.

### **5.4 Li Perchlorate and Other Perchlorates**

Suppliers to Sea-Bird Scientific are required to inform Sea-Bird Scientific if any of the parts and materials supplied to Sea-Bird Scientific contains any perchlorates. Specifically, the presence of perchlorate which is primarily found in lithium button cell batteries used as memory back up. Additionally, suppliers to Sea-Bird Scientific are required to inform Sea-Bird Scientific of the presence of any perchlorate at greater than 6 ppb in any part or material supplied to Sea-Bird Scientific.

## 5.5 DEHP

- 1) Only for parts and components intended for Medical Devices.
- 2) Suppliers to Sea-Bird Scientific are required to inform Sea-Bird Scientific if any of the parts and materials contains DEHP above 0.1% w/w.

## Annex I – Requirements (Summary)

Restrictions		
Regulation	Under Scope	Materials/Components
ROHS DIRECTIVE RECAST (2011/65/EU)	PARTS, COMPONENTS AND PACKAGING INTENDED FOR ELECTRICAL OR ELECTRONIC PRODUCTS	Maximum 1000 ppm: Pb, Hg, Cr 6+, PBB, PBDE. Maximum 100 ppm: Cd.
REGULATION 276/2010 AMENDING THE REACH REGULATION 1907/2006	ALL HOMOGENEOUS PARTS & MATERIALS	Dibutyl tin above 1,000 ppm
MONTREAL PROTOCOL	ALL PARTS & MATERIALS	Ozone Depleting Substances
SECTION 1502 OF DODD- FRANK	ALL 3TGS PROVIDED TO SEA-BIRD SCIENTIFIC NEED TO BE CONFLICT FREE BY 1 JANUARY 2015	Tin, tantalum, tungsten, and gold (3TGs)
21CFR801.437 US FDA USER LABELING FOR DEVICES CONTAINING LATEX	PARTS, COMPONENTS AND PACKAGING INTENDED FOR MEDICAL DEVICES	Natural Latex Rubber
FRENCH BPA IN FOOD LAW	PARTS, COMPONENTS AND PACKAGING INTENDED FOR MEDICAL DEVICES (FLUID CONTACTING)	DEHP and Bisphenol A (BPA)
3A (DAIRY)	PARTS, COMPONENTS INTENDED FOR USE WITH DAIRY PRODUCTS (FLUID CONTACTING)	ANY SUBSTANCE ON STANDARD LIST THAT CONTACTS MILK)
LOW VOLTAGE DIRECTIVE (2006/95/EC)	SAFETY CRITICAL PARTS AND MATERIALS AS SPECIFIED ON PRODUCT SAFETY LISTS SPECIFIED	AS STATED ON PRODUCT SAFETY DRAWINGS AND LISTING REPORTS
ATEX/HAZ-LOC (94/9/EC)	SAFETY CRITICAL PARTS, MATERIALS & ASSEMBLIES AS SPECIFIED BY APPLICABLE SAFETY STANDARDS	AS STATED ON PRODUCT SAFETY DRAWINGS AND LISTING REPORTS
Material/Component Declaration / Certification – Upon Request		
Regulation	Under Scope	Materials/Components
DIRECTIVE 2002/95/EC ROHS DIRECTIVE	ALL COMPONENTS AND MATERIALS INTENDED FOR ELECTRICAL PRODUCTS	Maximum 1000 ppm: Pb, Hg, Cr 6+, PBB, PBDE. Maximum 100 ppm: Cd.
REGULATION 1907/2006 REACH REGULATION	ALL PARTS & MATERIALS	REACH SVHC Candidate List



SECTION 1502 OF DODD- FRANK	ALL 3TG CONTAINING PARTS OR MATERIALS – EICC-GESI DECLARATION	Tin, tantalum, tungsten, and gold (3TGs)
STANDARD SJ/T 11364-2006 CHINA ROHS	ALL COMPONENTS AND MATERIALS INTENDED FOR ELECTRICAL PRODUCTS	Maximum 1000 ppm: Pb, Hg, Cr 6+, PBB, PBDE. Maximum 100 ppm: Cd.
DIRECTIVE 93/42/EEC MEDICAL DEVICE DIRECTIVE	PARTS & COMPONENTS INTENDED FOR MEDICAL DEVICES (FLUID CONTACTING)	Phthalates which are classified as carcinogenic, mutagenic or toxic to
(MDD)		reproduction, of category 1 or 2, in accordance with Annex I to Directive 67/548/EEC,
HEALTH CANADA DEHP AND BPA NOTIFICATION	PARTS & COMPONENTS INTENDED FOR MEDICAL DEVICES	DEHP above 0.1% w/w, Bisphenol A (BPA)
3A (DAIRY)	PARTS, COMPONENTS INTENDED FOR USE WITH DAIRY PRODUCTS (FLUID CONTACTING)	ANY SUBSTANCE ON STANDARD LIST THAT CONTACTS MILK)
LOW VOLTAGE DIRECTIVE (2006/95/EC)	SAFETY CRITICAL PARTS AND MATERIALS AS SPECIFIED ON PRODUCT SAFETY LISTS SPECIFIED	AS STATED ON PRODUCT SAFETY DRAWINGS AND LISTING REPORTS
ATEX/HAZ-LOC (94/9/EC)	SAFETY CRITICAL PARTS, MATERIALS & ASSEMBLIES AS SPECIFIED BY APPLICABLE SAFETY STANDARDS	AS STATED ON PRODUCT SAFETY DRAWINGS AND LISTING REPORTS
<b>COMMUNICATION REQUIREMENTS – If Present</b>		
Regulation	Under Scope	Materials
REGULATION 1907/2006 REACH REGULATION	ALL PARTS & MATERIALS	Must declare all REACH SVHC's on The ECHA SVHC Candidate List
IMERC US STATE REGULATIONS ON MERCURY IN PRODUCTS	ALL PARTS & MATERIALS	Any intentionally added Hg
CALIFORNIA PERCHLORATE BEST MANAGEMENT PRACTICES FOR PERCHLORATE	ALL PARTS & MATERIALS (GENERALLY LITHIUM BUTTON CELL BATTERIES)	Lithium perchlorate content
CALIFORNIA PROPOSITION 65 SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT	ALL PARTS & MATERIALS	Substances found on the OEHHA Proposition 65 Substance List

3A (DAIRY)	PARTS, COMPONENTS INTENDED FOR USE WITH DAIRY PRODUCTS (FLUID CONTACTING)	ANY SUBSTANCE ON STANDARD LIST THAT CONTACTS MILK)
LOW VOLTAGE DIRECTIVE (2006/95/EC)	SAFETY CRITICAL PARTS AND MATERIALS AS SPECIFIED ON PRODUCT SAFETY LISTS SPECIFIED	AS STATED ON PRODUCT SAFETY DRAWINGS AND LISTING REPORTS
ATEX/HAZ-LOC (94/9/EC)	SAFETY CRITICAL PARTS, MATERIALS & ASSEMBLIES AS SPECIFIED BY APPLICABLE SAFETY STANDARDS	AS STATED ON PRODUCT SAFETY DRAWINGS AND LISTING REPORTS