



**DATE:** January 2025

**TO:** Contec, Inc Customers

Dear Customer:

Though Contec has not specifically tested for all substances referenced in the statements below, based on a review of our raw materials, manufacturing and packaging processes, and finished products, we consider the information provided to be accurate.

### **REACH SVHC**

Based on a review of the Contec processes for the manufacture of Contec® products, we maintain there are no (0) substances from the REACH SVHC (Substances of Very High Concern) list present at regulated quantities in the products Contec manufactures and/or distributes.

### **TSE/BSE/PORCINE/BOVINE**

This is to certify the products Contec manufactures and distributes are produced entirely from materials of synthetic origin and therefore are free from human or any other animal derived materials including bovine and/or porcine products. In addition, there are no animal derived components used in the manufacturing or handling processes of this product. Therefore, Contec only produces products which can be declared free of Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE). This is pursuant to the reference standard titled Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products (EMA/410/01 Rev. 3).

### **PFAS**

Per- and polyfluoroalkyl substances (PFASs, also perfluorinated alkylated substances) are synthetic organofluorine chemical compounds containing multiple fluorine atoms attached to an alkyl chain. This group of chemicals contains thousands of substances. They are persistent in nature and can cause severe health risks including various types of cancer. PFOA and PFOS belong to PFAS subgroup of perfluoro surfactants.

Although we have not analyzed for every raw material or finished good for PFAS, based on a review of raw materials and our process for the manufacture of Contec parts there are no parts which incorporate PFAS.

### **RESTRICTION OF HAZARDOUS SUBSTANCES (RoHS)**

Contec, Inc. has reviewed the Restriction of Hazardous Substances (RoHS) directive and is in compliance, as Contec does not sell electrical or electronic products, equipment, sub-assemblies, cables, components or spare parts.

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*"EU Directive 2011/65/EU (Restriction of the Use of Certain Hazardous Substances in Electronic and Electrical Equipment) restricts the amount of hazardous substances that can be used in the manufacture of electrical and electronic equipment (EEE)."*

The Directive bans anyone from placing on the EU market EEE in which any homogeneous material contains more than the tolerated maximum concentration values (MCVs) of six substances:

- lead (Pb)
- mercury (Hg)
- hexavalent chromium (Cr(VI))
- cadmium (Cd)
- polybrominated biphenyls (PBB)
- polybrominated diphenyl ether (PBDE)

Following a review, the following four additional substances have now been confirmed for inclusion in the RoHS Directive (as early as 22 July 2019):

- Bis (2-ethylhexyl) phthalate (DEHP)
- Butyl benzyl phthalate (BBP)
- Dibutyl phthalate (DBP)
- Diisobutyl phthalate (DIBP)

Based on a review of the Contec processes for the manufacture of Contec® products, we maintain there are no (0) restricted substances from the RoHS directive present in regulated quantities in the products Contec manufactures and distributes.

## **METAL RESIDUES and ELEMENTAL IMPURITIES**

EMA Guidelines on the Specification Limits for Residues of Metal Catalysts or Metal reagents – EMEA/CHMP/SWP/4446/2008)

ICH guidance for industry Q3D Elemental Impurities

Contec does not manufacture, distribute, or sell any marketed drug products. Contec also does not use any type of metal catalysts or metal reagents to change the rate of any chemical reactions as defined below:

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*Metal catalysts and metal reagents are defined here as chemical substances that are used to change the rate of chemical reactions or which act on other chemical substances in chemical reactions. For the purpose of this guideline, metal catalysts and metal reagents refer to metals used in the synthesis of the active pharmaceutical ingredient, the synthesis of any of the pharmaceutical excipients, or the synthesis of any of the pharmaceutical excipients used during the manufacture of the drug product but no longer present in the drug product itself. Metal residues can either be present in the original form of the metal or as a form of the metallic element altered by downstream chemical processing.*

*ICH guidance for industry Q3D Elemental Impurities contains recommendations for manufacturers of human drugs and biologics on applying a risk-based approach to control elemental impurities and PDE.*

*ICH Q3D recommends that manufacturers conduct a product risk assessment by first identifying known and potential sources of elemental impurities. Manufacturers should consider all potential sources of elemental impurities, such as elements intentionally added, elements potentially present in the materials used to prepare the drug product, and elements potentially introduced from manufacturing equipment or container closure systems.*

Although we have not analyzed for metal residue or elemental impurity included in the EMA Guidelines and ICH guidance for industry, based on a review of our processes for the manufacture of Contec products, there are no metal residues or elemental impurities present in the parts Contec supplies.

#### **NITROSAMINE**

Although Contec has not analyzed or specifically tested for Nitrosamine in the finished goods, based on a review of our processes and raw materials Contec has no reason to believe nitrosamine is present in the product.

#### **ALLERGENS, PHTHALATES, GMO, PFOS, BPA**

Although Contec has not analyzed or specifically test for every allergen, phthalates (used in making plastic goods), GMO (genetically modified organisms), PFOS (Perfluorooctanesulfonic acid) or Bisphenol-A (BPA), based on a review of our processes and raw materials Contec has no reason to believe allergens, phthalates, GMO and/or PFOS are present.

#### **RARE EARTH METALS FROM CHINA**

Contec does not source, use or manufacture with any of the below mentioned elements:

- cerium (Ce)
- dysprosium (Dy)
- erbium (Er)
- europium (Eu)
- gadolinium (Gd)
- holmium (Ho)

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- lanthanum (La)
- lutetium (Lu)
- neodymium (Nd)
- praseodymium (Pr)
- promethium (Pm)
- samarium (Sm)
- scandium (Sc)
- terbium (Tb)
- thulium (Tm)
- ytterbium (Yb)
- yttrium (Y)

None of the products sold to customers would be impacted since these elements are not used in production or sourced from China.

#### **LATEX-FREE**

Contec, Inc products are produced with non-latex materials. Non-latex materials are materials which are not made with natural rubber latex.

#### **PERSISTENT ORGANIC POLLUTANT (POP)**

The Stockholm Convention on Persistent Organic Pollutants (POP) was adopted by the Conference of Plenipotentiaries on 22 May 2001 in Stockholm, Sweden. The Convention entered into force on 17 May 2004. The Stockholm Convention on Persistent Organic Pollutants is a global treaty to protect human health and the environment from chemicals that remain intact for long periods, become widely distributed geographically, accumulate in the fatty tissue of humans and wildlife, and have harmful impacts on human health or on the environment. As set out in Article 1, the objective of the Stockholm Convention is to protect human health and the environment from persistent organic pollutants.

Contec does not use POP substances in the use, manufacturing, importation, processing or distribution of its raw or finished goods.

#### **WOOD PALLETS**

Contec does not purchase or use wood pallets treated with 2,4,6-tribromophenol.

#### **TRIS(2,4-DITERT-BUTYLPHENYL) PHOSPHITE**

Based upon a review of the chemicals and materials used to produce the product, there are no Tris(2,4-ditert-butylphenyl)phosphite chemical substances found in the products Contec manufactures.

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### **PERFLUORINATED CHEMICALS (PFCs)**

Based upon a review of the chemicals and materials used to produce the product, there are no perfluorinated chemical substances found in the products Contec manufactures.

### **PERSISTENT BIOACCUMULATIVE TOXINS (PBTs)**

Based upon a review of the chemicals and materials used to produce the product, there are no persistent bioaccumulative toxins found in the products Contec manufactures.

### **RNAse/DNAse/PROTEASE**

Based on a review of the Contec processes for the manufacture of Contec® products, we maintain there are no (0) RNAse, DNAse and/or Protease present in the products Contec manufactures and distributes.

### **DEHP**

Based on a review of the Contec processes for the manufacture of Contec® products, we maintain there are no (0) Di-(2-ethylexyl) phthalate (DEHP) present in the products Contec manufactures and distributes.

### **MELAMINE**

Melamine is a basic component of a hard-wearing thermo-setting plastic used to make durable tableware, worktops and whiteboards. It is also used in the manufacture of fire retardants, fertilizers, pigments and flues. It was also found to be illegally added to human and animal food products to bolster the apparent protein content, or it has been added as an ingredient in processed food, which is intended to contain protein.

In accordance with the published FDA and European Union (EU) guidelines on Melamine, Contec has determined no at-risk compounds are used in the manufacturing process which could be contaminated with melamine.

### **LATEX**

Based upon a review of the chemicals and materials used to produce the product, there are no latex substances found in the products Contec manufactures and sells.

### **CONFLICT MINERALS**

As a global supplier Contec, Inc. is aware of our obligations with regards to laws and regulations regarding Conflict Minerals, specifically the Dodd-Frank Wall Street Reform and Consumer Protection Act, Section 1502. Contec, Inc. is committed to conducting its business worldwide with respect for human rights and in compliance with all applicable laws.

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None of the minerals named as "Conflict Materials" in the Act sourced from Democratic Republic of the Congo ("DRC") and in the adjoining countries ("DRC Region") are used in the manufacturing of any Contec, Inc. products nor do we directly source or process conflict materials. We do not use any of the materials (tin, tungsten, tantalum, or gold) in our processes or finished goods.

Sincerely,

A handwritten signature in blue ink, appearing to read "Emily Phalen", is positioned below the word "Sincerely,".

Emily Phalen

Regulatory Affairs

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The information contained herein is to our best knowledge accurate and reliable as of the date of publication. Contec makes no warranties and makes no representations as to the accuracy or completeness of the information contained herein, and assumes no responsibility regarding the consequences of its use or for any printing errors.

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