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July 11th, 2023

Regulatory Fact Sheet

ReZalloy Rx 1135
ReZalloy Rx 1140
ReZalloy Rx 1140-LV
ReZalloy Rx 1150
ReZalloy Rx 1160

The following letter is provided in response to your request for information on the above-referenced Compounding Solutions' products. All Compounding Solutions' products are made in the USA at our facility located in Lewiston, Maine.

Please note that Compounding Solutions does not routinely analyze for additional substances that are not listed in the SDS. Unless otherwise indicated, the information provided herein is based upon information from raw material suppliers, product composition and Compounding Solutions' manufacturing process.

Bisphenol A (BPA)

CAS No.: 80-05-7

IUPAC name: 4,4'-dihydroxy-2,2-diphenylpropane

Based on a review of the final product composition and the specifications of the raw materials, these products are not known or expected to contain BPA.

Bovine Spongiform or Transmissible Spongiform Encephalopathy (BSE/TSE)

Animal derived materials are primarily a concern with regard to the infectious agent associated with Bovine/Transmissible Spongiform Encephalopathy (BSE/TSE). Based on a review of the raw materials, there are animal derived substances used in the manufacturing of at least one raw material. According to the manufacturer:

"...processing conditions used in the production of these tallow derivative substances are in



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compliance with the minimum conditions described below for the processing of rendered fats listed in Annex XIII, Chapter XI of the EU Regulation 142/2011/EC, Commission Regulation 722/2012, and the Notes for Guidance EMA/410/01 Rev 3.

Process Conditions: Regulation 142/2011/EC Annex XIII Chapter XI

- a) Transesterification or hydrolysis at at least: 200°C, under corresponding appropriate pressure, for 20 minutes (glycerol, fatty acids and esters); or
- b) Saponification with NaOH 12 M (glycerol and soap) in a batch process at 95°C for 3 hours, or in a continuous process at 140°C, 2 bars (2,000 hPa) for 8 minutes; or
- c) Hydrogenation at 160° C at 12 bars (12,000 hPa) for 20 minutes.

These conditions are considered to be sufficient to inactivate BSE (Bovine Spongiform Encephalopathy) and TSE (Transmissible Spongiform Encephalopathy) transmitters. The conditions also meet the requirements of ISO 22442-1:2007 Annex C.5 regarding the processing of tallow derivatives used in medical devices.

Additionally, these tallow derivative substances are compliant with the U.S. Food and Drug Administration regulations regarding the use of prohibited cattle materials in food (21 CFR § 189.5) and cosmetics (21 CFR § 700.27), as prohibited cattle materials do not include tallow derivatives.”

California Proposition 65

California Proposition 65, officially known as the Safe Drinking Water and Toxic Enforcement Act of 1986, was enacted as a ballot initiative in November 1986. The proposition 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. Based on the list of substances known to the state to cause cancer or reproductive toxicity (last updated April 21st, 2023), these products may contain the following substances at trace levels (< 1 ppm): styrene, 1,3-butadiene, methanol, and ethylbenzene.

CONEG

The Coalition of Northeastern Governors (CONEG) of the USA, along with European



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directive 94/62/EC on packaging and packaging waste, require that the sum of the concentration levels of lead, cadmium, mercury, and hexavalent chromium present in packaging or packaging components shall not exceed 100 ppm. Based on the product composition and a review of the raw materials, such substances are not expected to be present, nor are they intentionally added.

Conflict Minerals (Dodd-Frank Wall Street Reform & Consumer Protection Act)

All current Compounding Solutions' products meet the regulations implemented by the mandate of Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010. We confirm, to the best of our knowledge, the materials used in these products do not contain and are not derived from conflict minerals that originate in the Democratic Republic of the Congo and certain adjoining countries ("Covered Countries") and that help fund armed conflict and human rights abuses. "Conflict minerals" is a generic term that broadly refers to, collectively, columbite - tantalite (coltan), cassiterite, gold, and wolframite, including their derivatives tantalum, tin, and tungsten (regardless of their origin) and are also referred to as "3T+Gs" or "3TGs." As used in this policy statement, we refer to "conflict minerals" as those 3TGs that support armed conflict and other human rights abuses in the DRC.

It is our policy not to knowingly purchase any raw materials that contain conflict minerals that directly or indirectly finance or benefit armed groups in the Covered Countries. The supply chain associated with conflict minerals is complex and we have been working with our suppliers to determine the sources of the conflict minerals in the raw materials supplied to us. The responses that we have received to date indicate that none of the tantalum, tin, tungsten, or gold in the raw materials supplied to us is sourced from mines located in areas under the control of armed groups in the Covered Countries.

EU MDR

On 5 April 2017, the Medical Device Regulation (MDR) was adopted, and entered into force on 25 May 2017. Manufacturers of currently approved medical devices will have a transition time of three years until 26 May 2020 amended to have a transition time of one more year until 26 May 2021 to meet the requirements of the MDR as listed in the following, per Regulation (EU) 2017/745 of the European Parliament and of the Council of 5



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April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. Substances in the scope of this declaration are:

- Substances which have been identified as carcinogenic, mutagenic, or toxic to reproduction (CMR) categories 1A or 1B, in accordance with Part 3 of Annex VI of CLP Regulation (EC) No. 1272/2008.
- Substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health, and which are identified either in accordance with the procedure set out in Article 59 of Regulation (EC) No. 1907/2006 (REACH), or, once a delegated act has been adopted by the Commission pursuant to the first subparagraph of Article 5(3) of Regulation (EU) No 528/2012.

We confirm that the substances regulated by Regulation (EU) 2017/745, as stated in Section 10.4 on the restriction of the use of certain hazardous substances are, to the best of our knowledge, not found in the above products at a concentration greater than 0.1% weight by weight. Additionally, none of these substances are intentionally used in the processing or handling of the products. Therefore, we consider the substance restriction requirements of Regulation (EU) 2017/745 as fulfilled with no exemptions being considered.

FDA/Biocompatibility Status

Compounding Solutions certifies that ReZalloy Rx meets the requirements of L929 Neutral Red Uptake Cytotoxicity Testing and is not considered to have a cytotoxic effect. This study was based on the following references: ISO 10993-5, 2009, Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity; ISO 10993-12, 2012, Biological Evaluation of Medical Devices – Part 12: Sample Preparation and Reference Materials. Testing was performed by Labcorp, an ISO/IEC 17025 accredited laboratory, located in Bedford, MA.

FDA Food Allergens

The FDA "Food Allergen Labeling and Consumer Protection Act of 2004" has identified eight major foods or food groups--milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans--that account for 90% of food allergens. None of the eight listed allergens are known to be present in these products or their raw materials. Furthermore,



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there are no allergen containing materials used in or around the manufacturing and transport of these products.

Material Containing HAP(s)

Hazardous air pollutants (HAPs) are defined in Section 112(b) of the Clean Air Act Amendments of 1990. Materials that contain HAPs are defined under 40 CFR 63.11180 as materials that contain 0.1% or more by mass of any individual HAP that is an OSHA-defined carcinogen as specified in 29 CFR 1920.1200(d) (4), or 1.0% or more by mass for any other individual HAP. Please refer to section 3 of the SDS for the most current information regarding the presence of any HAP (as defined above) for the listed products.

Halogenated Flame Retardants

These products are not intentionally manufactured or formulated with halogenated or phosphorous based flame retardants; however, we do not analyze for these specific substances or compounds.

Latex-Free

According to 21 CFR 801.437, all devices composed of or containing, or having packaging or components that are composed of, or contain, natural rubber that contacts humans require labeling. The term "natural rubber" includes natural rubber latex, dry natural rubber, and synthetic latex or synthetic rubber that contains natural rubber in its formulation. Based on a review of the composition of the products and the specifications of the raw materials, these products are not known to contain latex, nor do they come into contact with any known materials containing latex.

Nanomaterials

These products are not intentionally manufactured or formulated with nanomaterials as defined under the EU Commission Recommendation of 18 October 2011 (2011/696/EU); however, we do not analyze for these specific substances or compounds.

Nickel

These products are not intentionally manufactured or formulated with nickel; however, we do not analyze for this specific substance or compound.



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Polybrominated Diphenylethers (PBDEs) Flame Retardant Chemicals

PBDEs (Polybrominated Diphenyl Ethers), also called “brominated flame retardants,” are a group of flame retardant chemicals that are added to foam padding, plastics and fabrics. Common PBDEs are pentaBDE (five bromine molecules), octaBDE (eight bromine molecules) and decaBDE (ten bromine molecules). Based on a review of the final product composition and the specifications of the raw materials, these products are not known or expected to contain any of the above-referenced PBDE chemicals.

Phthalates

Based on the final product composition and the specifications of the raw materials, these products are not known or expected to contain substances that are identified as phthalates. The chemical composition of this product fully complies with the requirements for the below mentioned substances according to EC Council Directive 2005/84/EC amending for the 22nd time Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (phthalates in toys and childcare articles):

Butyl benzyl phthalate (BBP, CAS No. 85-68-7);
Di-n-butyl phthalate (DBP, CAS No. 84-74-2);
Di(2-ethylhexyl)phthalate (DEHP, CAS No. 117-81-7);
Di-isononyl phthalate (DINP, CAS No. 28553-12-0);
Di-isodecyl phthalate (DIDP, CAS No. 26761-40-0);
Di-n-octyl phthalate (DNOP, CAS No. 117-84-0);
Diisobutyl phthalate (DIBP, CAS No. 84-69-5); and
Di-n-pentyl phthalate (DNPP, CAS No. 131-18-0).

Polyvinyl Chloride (PVC)

These products are not intentionally manufactured or formulated with polyvinyl chloride (PVC) (CAS No. 9002-86-2). Based on the final product composition and the specifications of the raw materials, these products are not known or expected to contain PVC.



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REACH - Annex XIV Authorization List

In accordance with the European Regulation 1907/2006 on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), a manufacturer, importer or downstream user shall not place a substance on the market for use or use it himself if that substance is included in Annex XIV unless it complies with the conditions set forth in Article 56 of 1907/2006/EC. Based on the final product composition and the specifications of the raw materials, these products are not known to contain any substances which are identified on the current listed 59 substances of Annex XIV (under REACH).

REACH - Annex XVII Restricted Substances

In accordance with Article 67 of the European Regulation 1907/2006 on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), a substance on its own, in a mixture or in an article, for which Annex XVII contains a restriction shall not be manufactured, placed on the market, or used unless it complies with the conditions of that restriction. Based on the final product composition and the specifications of the raw materials, these products are not known to contain substances which are identified on the current listed 71 restricted substances of Annex XVII (under REACH).

REACH - Substances of Very High Concern (SVHC)

In accordance with Article 59 of the European Regulation 1907/2006 on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), from time to time, the European Chemicals Agency (ECHA) publishes lists identifying substances of very high concern (SVHCs) (as defined in Article 57 of REACH and included in the REACH "Candidate List" for further regulation). Based on the final product composition and the specifications of the raw materials, these products are not known to contain substances at greater than 0.1% (reporting threshold) which are identified on the current listed 233 substances of very high concern (under REACH), including the most recent addition of nine new substances on 17-Jan-2023.

Restriction of Hazardous Substances (RoHS)

Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE) is referred to as *RoHS 1* and the recast Directive 2011/65/EU is referred to as *RoHS 2*, onto which 2015/863/EU was appended on March 31,



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2015 to create *RoHS 3*.

RoHS specifically restricts the concentration of the following materials in electric and electronic equipment to a level equal to or less than 0.1%: lead, hexavalent chromium (VI), polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), other polybrominated compounds. It further restricts the concentrations of cadmium and mercury present in the product to a level equal to or less than 0.01% by weight. *RoHS 3* added the restriction of the following phthalates at concentrations greater than 0.1% threshold: bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), and diisobutyl phthalate (DIBP).

Based on the final product composition and the specifications of the raw materials, no RoHS substances are known or expected to be present.

If you need any further information, please feel free to contact your account manager or customer service representative.

Best Regards,

A handwritten signature in black ink that reads 'Erin Hu'.

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Regulatory Statement Disclaimer

The absence of the listed substances of interest, either in this document or in related regulatory documents accompanying this document, has not been verified by analysis or tests performed by Compounding Solutions and is declared based on the information available to us from our raw material suppliers. The information we receive from our suppliers is information which they are legally obliged to share with their downstream users. It can therefore not be excluded that trace levels of these substances may be unintentionally present (amongst others because they may be ubiquitous in the environment) or may result from the specific characteristics of the raw materials or the manufacturing process. It is the responsibility of the recipient of our products to ensure that any local applicable rules and legislation are observed.

This document and related documents accompanying this document are valid until the next relevant legislative and/or regulatory change.

To the best of our knowledge, the information contained in this statement is accurate and reliable as of the date of publication. The information relates only to the products specifically identified in this document (or documents intentionally accompanying this document) when not used in combination with any other products or materials. Compounding Solutions makes no warranties, express or implied, and assumes no liability in connection with any use of this information. Upon sale of Compounding Solutions products, Compounding Solutions warrants that the products confirm to the applicable written specifications at the time the products are shipped from Compounding Solutions' facility. All other express or implied warranties, including, without limitation, the implied warranties of merchantability and fitness for a particular purpose, are disclaimed. Purchaser acknowledges that it has sole control and responsibility to ensure, on a continuing basis, that the products and any method of use or application of the products are suitable for its purposes. Any assistance provided by Compounding Solutions to purchaser relative to the product, including without limitation, formulation, manufacturing and testing for the use or application of the products for purchaser's purposes, is made without any express or implied warranties, including, without limitation, the implied warranties of merchantability and fitness for a particular purpose. Compounding Solutions will not be liable for consequential or indirect damages.

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