



The Best Home a Drug Can Get™

Effective Date: Apr. 25, 2022

Expiration Date: Earlier of one year of change to law(s) cited below.

## **Re: Cellgyn® Regulatory Information**

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### **Animal Derivatives (BSE/ TSE)**

Based on the information provided to SANISURE by its raw material suppliers and review of our product formula and our materials handling and processing procedures, we have been able to determine that the product listed above does not contain ingredients derived from animals including animal fats (tallow).

Based on this information there would be no known sources of Bovine Spongiform Encephalopathy (BSE) or Transmissible spongiform encephalopathy (TSE).

### **ISO 10993-4 and ISO 10993-5**

Based on the information provided to SANISURE by its raw material suppliers, we have been able to determine that the product listed above is non-hemolytic (10993-4) and non-cytotoxic (10993-5).

### **Presence of Substances - Genetically Modified Organisms (GMO's)**

A genetically modified organism (GMO) is Defined as any organism whose genetic material has been altered using genetic engineering techniques. Based on the information provided to SANISURE by its raw material suppliers and our formulation reviews, we have found that GMO's may be present in the SANISURE product listed above as a result of specific characteristics of the raw materials utilized by SANISURE's supplier(s) and/or of their manufacturing process(es).

### **Regulatory Compliances**

Based on the information made available to us by our raw material supplier, the above material is compliant to the below list of regulatory requirements.

- RoHS Compliant
- REACH Compliant (223 SVHC)
- Conflict Minerals
- California Proposition 65

## Storage Conditions and Shelf Life

The recommended shelf life of the above-mentioned product is five (5) years from the date of manufacturing. This applies to new and unused product utilizing the following storage conditions: Store the product in a dry inside environment with an ambient temperature below 77°F and humidity of less than 65%. The product should be free from exposure to direct outside weather influences and stored in a dark space out of direct contact with light. The area should be free from volatile solvents, corrosive gases, or other potentially harmful vapors.

## Substances

Based on the information made available to us by our raw material supplier, we have found that the product listed above does not intentionally contain the following substances:

- **Bisphenol A (BPA)**
- **Latex**
- **Melamine**
- **Phthalates (plasticizers)**
  - Benzyl butyl phthalate (BBP)
  - Dibutyl phthalate (DBP)
  - Bis (2-ethylhexyl) phthalate (DEHP)
  - Di-isononyl phthalate (DINP)
  - Di-isodecyl phthalate (DIDP)
  - Di-isobutyl phthalate (DIBP)
  - Di-n-octyl phthalate (DNOP)
  - Di-n-hexyl phthalate (DnHP)
- **Polyvinyl Chloride (PVC)**
- **Per- and Polyfluoroalkyl substances (PFAS) including**
  - Perfluorooctanoic acid (PFOA)
  - Perfluorooctane sulfonate (PFOS)
- **Perfluorochemicals (PFCs)**

## USP Class VI, ISO 10993

- 1) Has been tested according to:
  - a. US Pharmacopoeia <88> in vivo Biological Reactivity Tests
- 2) The test article met the requirements of a USP Plastic Class VI
  - a. ISO 10993: Biological Evaluation of Medical Devices

The information submitted is valid as of the date of this letter. SANISURE makes no representations or warranties as to the accuracy of the information contained or referenced herein as of any other date. If you have any questions concerning this matter or if we can be of further assistance, please do not hesitate to contact us. Please contact your SANISURE Corporation Sales Representative should you need additional product support.

Sincerely,

*David Alexander*

David Alexander

Quality Manager

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