

# Product Regulatory Information Packet

**Product: AF Gentian Root (1:2) in Glycerin**

**Product ID #: RD9112**

---

## **Allergens:**

**The following food allergens are NOT present in this product:**

Wheat or wheat derivatives, Milk/Dairy Products, Fish (e.g. salmon, cod, flounder), Crustacean Shellfish (e.g. shrimp, lobster, crab), Soy or soy derivatives, Peanuts, Tree Nuts (e.g. almonds, cashews), Egg or egg derivatives, Corn or corn derivatives, Sodium, Cereals (e.g. spelt, rye, barley, oats), Celery, Mustard, Sesame seeds, Lupin, Sulfur Dioxide/Sulfites, Mollusks, Yeast or yeast derivatives

**The following food allergens are present in this product:**

None

**Cosmetic allergens NOT present in this product:**

This product does not contain any of the 83 substances listed in the EU Cosmetics Regulation 2023/1545

---

## **Genetically Modified Organisms:**

Bio-Botanica, Inc. confirms that none of the ingredients used in its preparation or manufacturing of the above-mentioned product has been subject to or derived from genetically modified sources. It is also free from both genetically modified DNA and the proteins derived from genetically modified DNA.

Therefore, this product is non-GMO.

---

## **Vegan/Vegetarian:**

Bio-Botanica, Inc. confirms that the above-mentioned product is vegetarian/vegan. No raw materials with animal derivatives have been used in the manufacturing of this product.

---

## **BSE/TSE Statement:**

Bio-Botanica, Inc. certifies that the ingredients in the above-mentioned product are not derived in whole or part from animal sources and does not utilize animal derivatives in its manufacture. Additionally, this material complies with the FDA interim rule effective January 12, 2004 (9 CFR Parts 309, 310, 311, 318 and 319) regarding prohibition



## Product Regulatory Information Packet

of Specified Risk Material (SRM) for human food and Requirements for the Disposition of Non-Ambulatory Disabled Cattle. This product is non-BSE & non-TSE.

---

### **Prop 65:**

Bio-Botanica, Inc. confirms that the above-mentioned product is compliant with the State of California's Proposition 65; whereas, to the best of our knowledge, this product does not contain any chemical known to the State of California to cause cancer, birth defects or other reproductive harm.

---

### **Animal Testing/Cruelty Free:**

Bio-Botanica, Inc. confirms that the above-mentioned product has not been subject to animal testing and is considered cruelty free.

---

### **GRAS Status:**

Bio-Botanica, Inc. confirms that the above-mentioned product is formulated with ingredients that are considered Generally Recognized as Safe (GRAS) when used in accordance with good manufacturing practices in food and beverage products.

---

### **Gluten:**

Bio-Botanica, Inc. confirms that the above-mentioned product is gluten free and has not been formulated or exposed to gluten-containing grains such as wheat, rye, barley, or oats.

---

### **CMR Statement:**

This is to certify that above-mentioned product manufactured by Bio-Botanica is CMR (Carcinogenic, Mutagenic or Toxic for Reproduction) free.

---

### **Natural Certification:**

Bio-Botanica, Inc. confirms that the above-mentioned product complies with the FDA's informal definition for "Natural" which states that nothing artificial or synthetic has been included or added.

---





## Product Regulatory Information Packet

### **RSPO Statement:**

Bio-Botanica, Inc. confirms that the product mentioned above is made with Glycerin that is derived from RSPO certified Palm Oil.

---

### **Non-Irradiation/ETO Statement:**

Bio-Botanica, Inc. confirms that the materials used in the manufacture of the above-mentioned product have not been handled by, exposed to, or have been treated with irradiation, Ethylene Oxide (ETO), nor sewage sludge. This statement is based on supplier information, routinely updated by Bio-Botanica.

---

### **PFA, Microplastics, and Nitrosamines Statement:**

Bio-Botanica, Inc. confirms that based on the manufacturing process of the above-mentioned product, the presence of PFAs, microplastics, and nitrosamines is not expected, nor are they intentionally added, even though these substances are not currently measured.

---

### **VOC Compliance Statement:**

Bio-Botanica, Inc. confirms that the materials used in the manufacture of the above-mentioned product are VOC Compliant.

---

### **Nanomaterial Statement:**

Bio-Botanica, Inc. confirms that the above-mentioned is not manufactured or formulated with Nanomaterials.

---

### **Phthalate Statement:**

Bio-Botanica, Inc. confirms that the above-mentioned is not manufactured or formulated with Phthalates.

---

### **PEG-Free Statement:**

Bio-Botanica, Inc. confirms that the above-mentioned is not manufactured or formulated with Polyethylene Glycol.

---

## Product Regulatory Information Packet

### **Preservative-Free Statement:**

Bio-Botanica, Inc. confirms that the above-mentioned is not manufactured or formulated with preservatives and is considered preservative-free.

---

### **Paraben Statement:**

Bio-Botanica, Inc. confirms that no parabens were added to the above-mentioned product during the manufacture, storage, and packaging operations.

To the best of our knowledge, this product is paraben free.

---

### **Pesticide Statement:**

Bio-Botanica, Inc. confirms that there are no potential sources of pesticides in any of the ingredients in the above-mentioned product. We conduct random pesticide screening as per customer requirements. If the customer requires such testing, a special request must be made. Adequate time must be provided for accurate results.

---

### **SVHC Statement:**

Bio-Botanica, Inc. confirms that the above-mentioned product does not contain any of the 240 Substances of Very High Concern (SVHC) identified by the REACH Regulation in their compositions.

---

### **Heavy Metal Impurities Report:**

| Heavy Metal  | Specification | Results   |
|--------------|---------------|-----------|
| Arsenic (As) | 10 ppm        | < 10 ppm  |
| Cadmium (Cd) | 4.1 ppm       | < 4.1 ppm |
| Lead (Pb)    | 0.5 ppm       | < 0.5 ppm |
| Mercury (Hg) | 0.3 ppm       | < 0.3 ppm |

---

*The above statements are based on supplier information, routinely updated by Bio-Botanica.*

Botanical Extracts  
Tinctures  
Nutraceuticals  
Cosmetic Intermediates  
Phytochemicals  
Spray Drying  
Product Development



**BIO-BOTANICA, INC.**

## Product Regulatory Information Packet

*Sophia Imanov*

**Sophia Imanov**

Regulatory Affairs Supervisor

Bio-Botanica Inc.



BIO-CHELATED®  
COLD EXTRACTION PROCESS

