

# **SODIUM DECANOATE**

## **GMP, BET, EXCIPIENT**

**CAS #: 1002-62-6**
**Formula: C<sub>10</sub>H<sub>19</sub>NaO<sub>2</sub>**
**F.W.: 194.25 g/mol**
**NDEC-3201**
**Bio EXCIPIENT GRADE**

ANALYSIS	SPECIFICATIONS	
Appearance and Color	White to Off White Powder	
Assay, Dried Basis	95.0 – 105.0%	
Elemental Impurities	Complies with USP <232>	
Endotoxin	< = 20.0 EU/g	
Identification, IR	Conforms to Reference Standard	
Impurities	Any Single Impurity	< = 1.0%
	Sodium Octanoate (Octanoic Acid)	Report
	Sodium Nonanoate (Nonanoic Acid)	Report
	Total Impurities	< = 3.0%
Iron (Fe)	Report	
Loss on Drying	< = 5.0%	
Microbial Content	TAMC	< = 100 CFU/g
	TYMC	< = 100 CFU/g
pH (10%)	9.0 – 11.0	
Residual Solvents	Ethanol	< = 5000 ppm
Sodium Quantification	Report	
Solubility	Passes Test	
Water, KF	< = 5.0%	

[Click here to view SDS, CoAs and other supporting regulatory documents on our website.](#)

### **General Product Overview**

Sodium Decanoate, or Sodium Caprate, is the sodium salt of capric acid, a 10-carbon saturated fatty acid. It has amphiphilic character and can form micelles and liquid crystalline phases in aqueous solution. Sodium Decanoate's properties may help elucidate the transport of biologically active molecules and as a final component of a finished drug product, it may serve to enhance the bioavailability of the API. BioSpectra's Bio Excipient Grade of Sodium Decanoate is supported by a Type IV drug master file submitted with the FDA.

### **Industry Application**

Suitable for use as a cGMP chemical in pharmaceutical manufacturing processes and products.

### **Key Product Features**

- The manufacturing of Sodium Decanoate is performed at BioSpectra's Bangor, PA facility.
- Appears as a white to off-white powder
- Manufactured in accordance with ICH Q7
- Manufactured in an enzyme free, hormone free and animal free environment
- Contains no known major food allergens (as defined by FDA and WHO)
- The final product and its raw materials are not derived from nor come into contact with animal parts, animal products, and/or animal byproducts or derivatives.
- Is not subject to genetic modification
- Synonyms: Capric Acid, Sodium Caprate, Decanoic Acid

### **Storage and Shipping Conditions**

Refer to SDS.

### **Standard Shelf-Life Policy**

Unless otherwise noted on the Shelf-Life Statement and CoA, this product has a 2-year retest date supported by a 3-year ICH Q1 Stability Study (if one is completed).

### **Package Sizes**

5kg, 10kg, and 25kg pails

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