

SODIUM DECANOATE

BET*, GMP, ACTIVE USFDA TYPE IV DMF

CAS #: 1002-62-6

Formula: C₁₀H₁₉NaO₂

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%

*Bioburden and Endotoxin Tested

[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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