BIOSPECTRA
Premium Pharmaceutical Ingredients

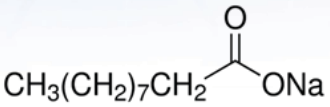
Excipient

ICH-Q7 GMP Manufactured Product

SODIUM DECANOATE, Blend Batch, GMP, Excipient Grade

INTENDED FOR USE AS AN EXCIPIENT

Sodium Decanoate – Blend Batch, is a blend of multiple production batches to provide the end-user with a larger blended, uniform Lot size. Sodium Decanoate, or sodium caprate, is the sodium salt of caproic 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.



CAS #: 1002-62-6
Formula: $C_{10}H_{19}NaO_2$
F.W.: 194.25 g/mol.
Solubility in Water (g/L): 0.1

BIO EXCIPIENT GRADE | Product Code: NDEC-3320 | Previously: ND3320

$C_{10}H_{19}NaO_2$ • F.W. 194.25 g/mol. • CAS# 1002-62-6

Made in the USA

These are general specifications. BioSpectra will customize our products to meet your quality based requirements.

ANALYSIS	SPECIFICATIONS
Appearance	White to off-white powder
Assay (Dried basis)	97.0% – 103.0%
Identification (IR)	Passes Test
Loss on Drying (LOD)	3.0% max.
pH (10%)	9.0 – 11.0
Single Impurities (GC)	≤ 1.0%
Sodium	Passes Test
Solubility in Water	Passes Test
Water (KF)	1.5% - 3.0%

General Product Description:

- The manufacturing of Sodium Decanoate NDEC-3320 is performed at BioSpectra's Bangor, PA facility utilizing multiuse equipment.
- Sodium Decanoate is a White to off-white powder
- Molecular Formula: $C_{10}H_{19}NaO_2$
- Molecular Weight: 194.25 g/mol.
- CAS Number: 1002-62-6
- There are no known major food allergens (as defined by FDA and WHO) in the manufacture of this product.

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BIOSPECTRA Key Compliance Attributes of BioSpectra Grades	Bio Excipient Grade ICH-Q7 Compliant Manufactured
Suitable for Research and Diagnostic	✓
Each Batch 100% Analyzed	✓
Management of Change	✓
Validated Analytical Methods	✓
Compendial Testing	✓
Trace Metals Analyzed	✓
Stability Testing Program	✓
BioSpectra Supply Chain Audit Trail	✓
Product Origin Statement	✓
Customer Quality Audits	✓
Validated Manufacturing Process	✓
US Manufactured at BioSpectra	✓
IPEC cGMP Compliant Manufactured	✓
Customized Additional Specifications	✓
Multi-Compendial Testing	✓
Low Bioburden Low Endotoxin (LBLE)	✓
Enzyme Tested	✓
Suitable for use as Excipient	✓
Microbial / Endotoxin Tested	✓
Manufactured in FDA Registered Facility	✓
Customized Manufacturing Schedule	✓
Custom Regulatory Packet	✓
Accelerated Stability	✓
Video Conference access to BioSpectra Sites	✓
Complete access to Product Traceability	✓
Access to Supply Chain Information	✓
ICH-Q7 Qualified Utilities	✓
ICH-Q7 Compliant Manufactured	✓
Type IV Drug Master File	✓

✓ indicates an attribute or level of compliance which is granted or available based on the purchase of the product grade.

Bio Excipient Grade: Intended for use as ICH-Q7 Compliant Excipient

LBLE: LBLE applies when product specifications include requirements for Bioburden Testing (TAMC/TYMC and/or Endotoxin).
LBLE stands for Low Bioburden, Low Endotoxin non-sterile products suitable for further use in parenteral manufacturing and other sterile applications.

Lead Time: Stock- 1 month / No Stock- 3 months
Minimum Order Quantity: Stock- 5kg / No Stock- 30kg

General Product Description:

- BioSpectra certifies that all Sodium Decanoate NDEC-3320 manufactured at BioSpectra and its raw materials are not derived from nor come in contact with animal parts, products and/or byproducts.
- Sodium Decanoate manufactured at BioSpectra and any raw materials used in the manufacture of Sodium Decanoate at BioSpectra are not subject to genetic modification.
- Synonyms: Sodium Caprate, Decanoic acid Sodium salt, Capric acid Sodium salt

GMP Compliance:

Bio Excipient Grade Sodium Decanoate NDEC-3320 is suitable for use as an excipient. It is manufactured in accordance with the ICH-Q7 Good Manufacturing Practice Guide. This grade of Sodium Decanoate is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

Retest Date:

The recommended retest period for Sodium Decanoate is two years from the date of manufacture.

Storage and Shipping Conditions:

Ship and Store between 2°C and 8°C. Store in a clean and dry area. Store in the original container.

Package Sizes:

1 kg bottle, 5 kg, 10 kg and 25 Kg pails