BIOSPECTRA
Premium Pharmaceutical Ingredients
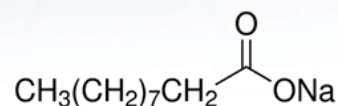
SODIUM DECANOATE

INTENDED FOR USE AS AN EXCIPIENT

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.

$$CH_3(CH_2)_7CH_2 - C(=O) - ONa$$

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 / ND3220

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

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 ND3220 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.

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

General Product Description:

- BioSpectra certifies that all Sodium Decanoate ND3220 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 ND3220 is manufactured in accordance with cGMP guidelines and is suitable to be used only as the following: ICH Q7 Compliant cGMP Manufactured Excipient for use in further Manufacturing. This Grade of Sodium Decanoate is not suitable to be used as an Active Pharmaceutical Ingredient, Drug Product or Household Item.

Expiration/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