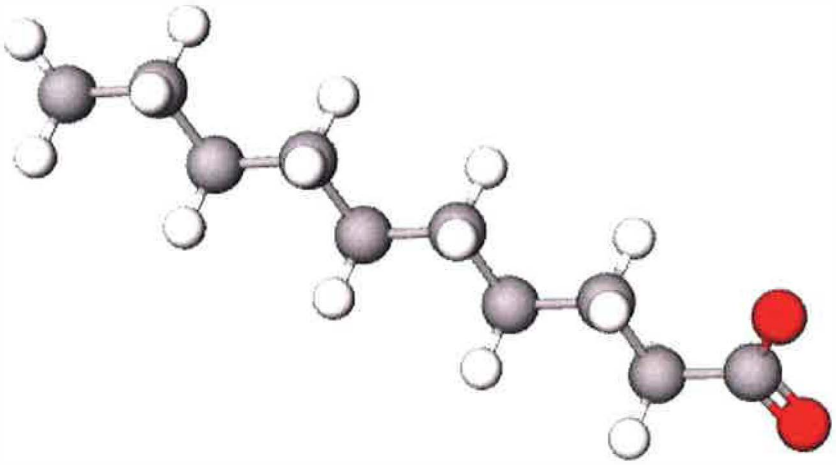
BIOSPECTRA
Premium Pharmaceutical Ingredients

SODIUM DECANOATE



BIO EXCIPIENT GRADE REGULATORY PACKET

Signature/Date:

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1. SODIUM DECANOATE, BIO EXCIPIENT GRADE

1.1. General Product Information

1.1.1. Product Name:
1.1.1.1. Sodium Decanoate
1.1.2. Product Code:
1.1.2.1. Historic: ND3201, ND3220, ND3320
1.1.2.2. Current: NDEC-3201, NDEC-3220, NDEC-3320
1.1.3. Scope:
1.1.3.1. This Regulatory Packet will provide the quality and regulatory information regarding the manufacturing, testing, packaging, storage, release, shipping, and handling of Bio Excipient Grade Sodium Decanoate manufactured by and at the BioSpectra Bangor, PA facility.
1.1.4. Molecular Formula:
1.1.4.1. $C_{10}H_{19}NaO_2$
1.1.5. Molecular Weight:
1.1.5.1. 194.25 g/mol

1.2. Manufacturing, Packaging, Release Site and Supplier Information

1.2.1. General Information:
1.2.1.1. BioSpectra manufactures Sodium Decanoate in its Bangor, PA facility. Sodium Decanoate is manufactured, packaged, stored, tested and released at BioSpectra's Bangor, PA facility.
1.2.2. Manufacturing:
1.2.2.1. The manufacturing of Sodium Decanoate is performed at BioSpectra's Bangor, PA facility utilizing multiuse equipment. Equipment used in the manufacturing of Sodium Decanoate is cleaned in accordance with BioSpectra's Cleaning Worksheet Procedure.
1.2.3. Packaging:
1.2.3.1. The packaging of Sodium Decanoate occurs in the following BioSpectra site: BioSpectra Bangor, PA Facility: 100 Majestic Way, Bangor, PA 18013
1.2.4. Testing for Release:
1.2.4.1. Testing and release of Sodium Decanoate is performed at the BioSpectra Bangor, PA Facility: 100 Majestic Way, Bangor, PA 18013
1.2.5. GMP Compliance Statement:
1.2.5.1. Bio Excipient Grade Sodium Decanoate 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.

1.3. Physico-Chemical Information

1.3.1. CAS Number:
1.3.1.1. CAS# 1002-62-6
1.3.2. Origin:
1.3.2.1. The origin of Sodium Decanoate is through chemical manufacturing using approved raw materials, which are further purified in accordance with ICH Q7 guidelines. Raw materials of synthetic and plant origin are used in the synthesis and purification of Sodium Decanoate.

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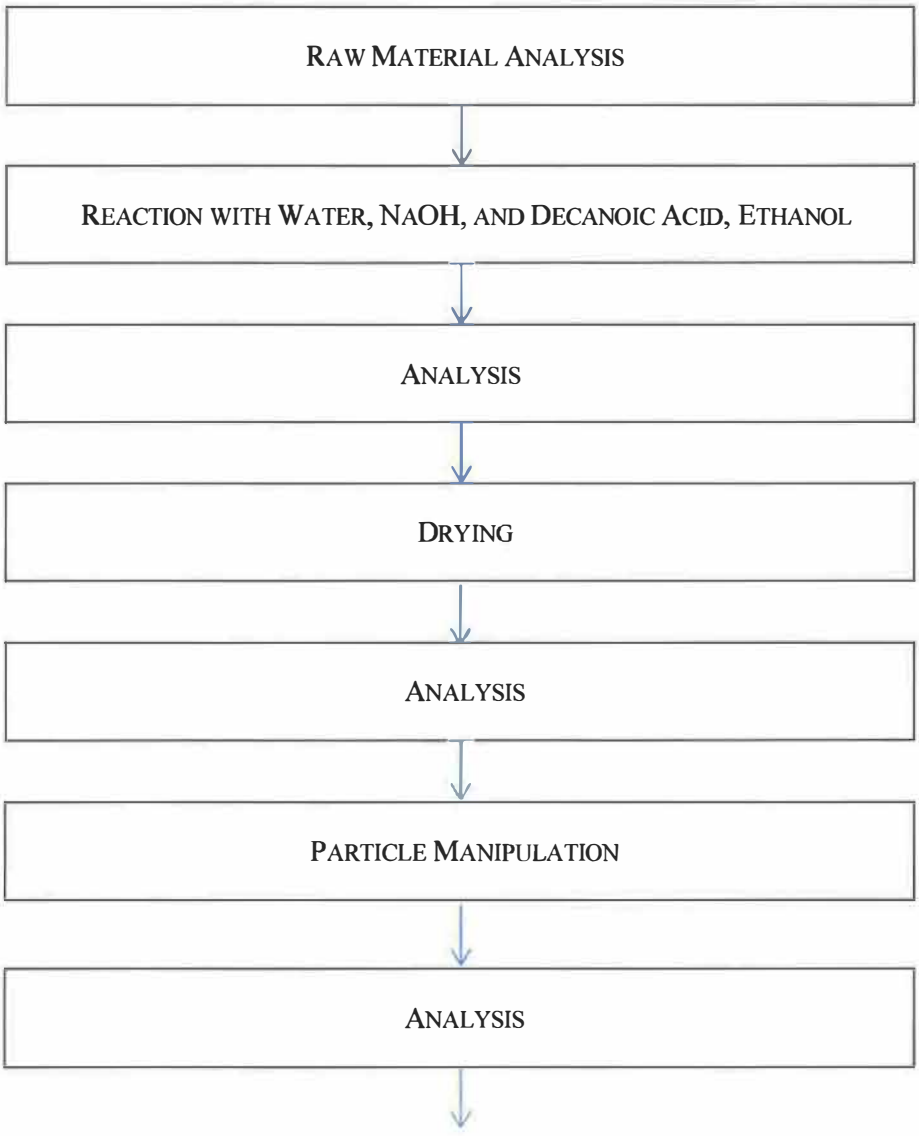
1.3.3. Synonyms:
- 1.3.3.1. Capric Acid, Sodium Salt
- 1.3.3.2. Sodium Caprate
- 1.3.3.3. Sodium Caprinate

1.3.4. Morphological Form:
- 1.3.4.1. White to off-white powder

1.3.5. Manufacturing Process:
- 1.3.5.1. The Sodium Decanoate, Bio Excipient Grade manufacturing process is performed by the following:

Approved Supplier Raw Material Synthesis



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PACKAGING

BioSpectra Excipient Manufacturing Process

BATCH SOLUTION CREATION

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PURIFICATION

↓

SPRAY DRYING

↓

TRAY DRYING (AS NEEDED)

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SODIUM DECANOATE FINAL PACKAGING

BioSpectra Excipient Manufacturing Process (Blend)

BATCH SOLUTION CREATION

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PURIFICATION

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SPRAY DRYING

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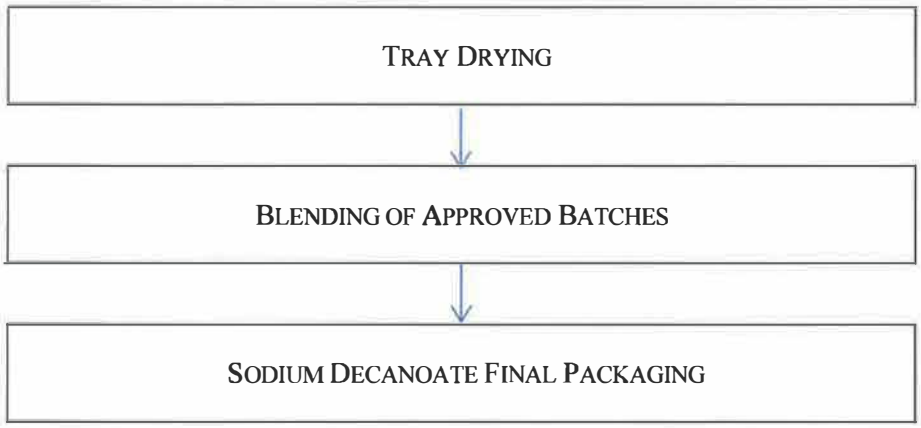

1.3.6. Specifications:
1.3.6.1. Available upon request.

1.4. Regulatory Information

1.4.1. Compendial Compliance:
1.4.1.1. Not Applicable
1.4.2. Master File:
1.4.2.1. Drug Master File (DMF) is currently not available for this product.
1.4.2.2. EDQM Certificate of Suitability is currently not available for this product.
1.4.3. REACH:
1.4.3.1. Refer to the Sodium Decanoate Safety Data Sheet for the REACH Number or contact your Commercial Team Representative for further information.
1.4.4. BSE/TSE Statement:
1.4.4.1. Sodium Decanoate has been evaluated for the source of the raw materials used in its production through the Supplier Qualification Program. BioSpectra can state that BSE/TSE is not a concern based on this evaluation. Sodium Decanoate, Bio Excipient Grade and its raw materials are not of animal origin.

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1.4.5. Allergens Statement:

1.4.5.1. Sodium Decanoate manufactured by BioSpectra and its raw materials are not manufactured with or using any of the following allergenic substances: Cereals containing gluten (i.e., wheat, rye, barley, oats, spelt, kamut or their hybridized strains) and products thereof, Crustaceans and products thereof, Eggs and products thereof, Fish and products thereof, Peanuts and products thereof, Soybeans and products thereof, Milk and products thereof (including lactose), Celery and products thereof, Mustard and products thereof, Sesame Seeds and products thereof, Lupin and products thereof, Molluscs and products thereof, Sulphur dioxide and sulfites at >10mg/kg as SO, Nuts i.e., Almonds (*Amygdalus communis* L.), Hazelnuts (*Corylus avellana*), Walnuts (*Juglans regia*), Cashews (*Anacardium occidentale*), Pecan nuts (*Carya illinoinenesis* (Wangenh.) K. Koch), Brazil nuts (*Bertholletia excelsa*), Pistachio nuts (*Pistacia vera*), Macadamia nuts and Queensland nuts (*Macadamia ternifolia*) and products thereof, Beef, Chicken, Pork, Azo Dyes, Benzoic Acid, Tartrazine, Vanillin, Cocoa, Cinnamon, Coriander, Yeast, Glutamate, Legumes, and Corn. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program.

1.4.6. Genetically Modified Organisms (GMO) Statement:

1.4.6.1. Sodium Decanoate has been evaluated for the source of the raw materials used in its production through the Supplier Qualification Program. BioSpectra can state that genetic modification is not a concern based on this evaluation.

1.4.7. Residual Solvents Statement:

1.4.7.1. BioSpectra can state based on the manufacturing process and the controlled handling, storage, and analysis of this product that the Sodium Decanoate manufactured by BioSpectra complies with the requirements and specifications listed in the current USP method <467> Tables 1, 2, 3, or 4. There are no Class 1, 2, 3, or other solvents used in the Sodium Decanoate manufacturing process, with the exception of the Class 3 solvent Ethanol which is utilized by BioSpectra's approved Raw Material Supplier and is removed during their manufacturing process. BioSpectra has confirmed this through the analysis of Sodium Decanoate for Ethanol during degradation and impurity profiling for manufacturing process validation, as well as through annual analysis of Sodium Decanoate for Ethanol.

1.4.8. Metal Catalyst and Metal Reagent Residues Statement:

1.4.8.1. BioSpectra can state that metal catalysts and metal reagents are not intentionally added or introduced to the BioSpectra manufacturing process for Sodium Decanoate, Bio Excipient Grade. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program, and can state that catalysts are not used in the raw material manufacturing process based on this evaluation.

1.4.9. Pallet Statement:

1.4.9.1. BioSpectra can state that the pallets used in the packaging and shipping of Sodium Decanoate, Bio Excipient Grade manufactured at BioSpectra are ISPM 15 compliant.

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1.4.10. Elemental Impurities Statement:

1.4.10.1. BioSpectra's Sodium Decanoate, Bio Excipient Grade material has been profiled for elemental impurities via ICP utilizing USP <232> and <233> in accordance with ICH Q3D. The results are reported in the associated Elemental Impurity Profile and are available upon request.

1.4.11. Melamine Statement:

1.4.11.1. BioSpectra does not intentionally add or use melamine in the BioSpectra manufacturing process of Sodium Decanoate, Bio Excipient Grade. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program, and can state that the raw materials are not expected to contain melamine based on this evaluation. BioSpectra additionally analyzes Sodium Decanoate annually for Melamine; Specification 2.5 mg/kg max.

1.5. Miscellaneous Product Information

1.5.1. Description of Batch:

1.5.1.1. The Sodium Decanoate process is a batch process where expected batch yields are established during validation in accordance with the Manufacturing Process Validation Master Plan. Individual batch yield is additionally determined for each manufactured batch and documented in the respective batch record.

1.5.2. Lot/batch numbering system:

1.5.2.1. The lot numbering system at BioSpectra employs the following format: 4 alphanumerical digits followed by a hyphen, 4 numerical digits followed by a hyphen, and finally 5 numerical digits. A sample lot number would appear as: NDEC-0123-00001

1.5.2.1.1. The first four digits are alpha digits which indicate the material manufactured, where NDEC represents Sodium Decanoate. The fifth and sixth digits are numeric digits which indicate the site of final material packaging, where 01 represents the Bangor, PA facility. The seventh and eighth digits are numerical digits which indicate the year the batch record was issued, where 23 represents 2023. The final five digits are sequential batch number where 00001 represents the first Sodium Decanoate batch of 2023 that is automatically generated by the ERP system. The sequential number automatically resets at the beginning of each calendar year.

1.5.3. Expiration date and/or recommended re-evaluation interval:

1.5.3.1. The current recommended retest or expiration date for Sodium Decanoate, Bio Excipient Grade is available in the BioSpectra Product Retest and Expiration Date List, DCN: BSI-LST-0239, and is based on current available stability data in accordance with BioSpectra's Stability Testing Program. Additionally, the recommended retest or expiration date will be available on the Product Specific Certificate of Analysis, as applicable.

1.5.4. Storage and shipping conditions:

1.5.4.1. Store in a tightly closed container in a dry, well-ventilated area away from incompatible substances.

1.5.4.2. Recommended storage temperature: 2-8°C.

1.5.5. Packaging:

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1.5.5.1. Packaging information is available through the following: https://Biospectra.us/packaging

1.6. Contact Information:

1.6.1. https://www.biospectra.us/about-us/commercial-marketing-team