



100 Majestic Way, Bangor, PA 18013

# TECHNICALLY UNAVOIDABLE PARTICLE PROFILE (TUPP) – SODIUM HYDROXIDE 10N SOLUTION

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## **1. PURPOSE:**

- 1.1. The purpose of this document is to provide the user of this product with a Technically Unavoidable Particle Profile (TUPP) for 10N Sodium Hydroxide manufactured in BioSpectra's Bangor, PA facility.

## **2. SCOPE:**

- 2.1. This TUPP applies to the manufacturing and packaging process of 10 N Sodium Hydroxide manufactured at BioSpectra's Bangor, PA facility.

## **3. REFERENCES:**

- 3.1. IPEC; Technically Unavoidable Particle Profile (TUPP) Guide

## **4. DEFINITIONS:**

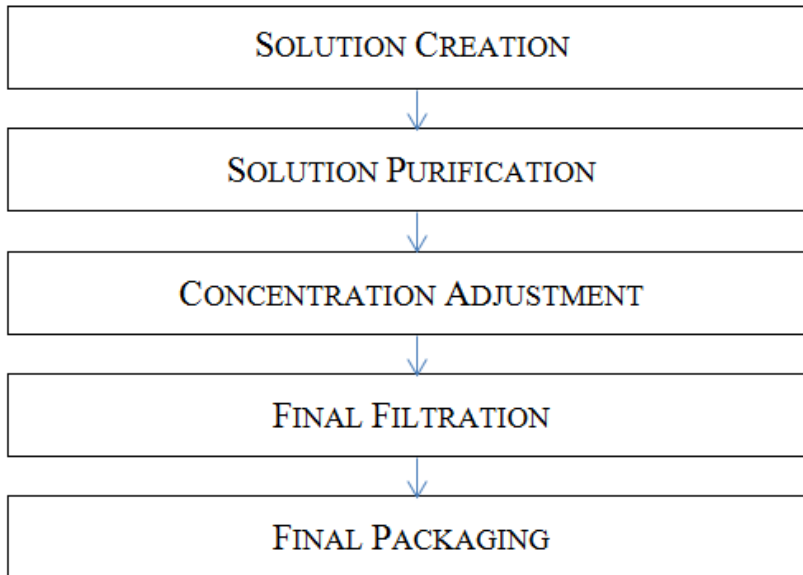
- 4.1. Technically Unavoidable Particle (TUP): A visibly different particle that can be viewed with the naked eye that is inherent to the raw material, manufacturing process or product and does not pose risk to patient safety.
- 4.2. Technically Unavoidable Particle Profiles (TUPPs): A report on all potential known Technically Unavoidable Particles (TUP) for an excipient process that can be shared with a customer or end user.
- 4.3. Atypical Particles – particles not consistent with the typical particulate profile; not previously encountered or identified.
- 4.4. Reprocessing: A system of improving an intermediate or finished product that does not conform to established specification by repeating a step or series of steps that are a part of the approved manufacturing process.
- 4.5. Polyvinyl chloride (PVC): A type of plastic polymer.
- 4.6. Chlorinated polyvinyl chloride (CPVC): A type of plastic polymer.
- 4.7. Ultra-high-molecular-weight polyethylene (U.H.M.W. PE): A type of plastic polymer.
- 4.8. High Density Linear Polyethylene (HDLPE): A type of plastic polymer.
- 4.9. Polytetrafluoroethylene (PTFE): A type of plastic polymer.
- 4.10. Fluorinated ethylene propylene (FEP): A type of plastic polymer.
- 4.11. Ethylene propylene diene monomer (EPDM): A synthetic rubber.

## **5. TECHNICALLY UNAVOIDABLE PARTICLES (TUP):**

- 5.1. The construction of a technically unavoidable particle profile assumes that GMPs are followed and possible mitigation strategies are taken, the remaining particles, if they pose no risk to safety, are deemed technically unavoidable.
- 5.2. Technically unavoidable particles could originate from any of the following parts of the manufacturing process: Material of Construction of the manufacturing equipment that is product contacting, consumable process equipment, Material of Construction of the packaging components and any materials that are involved in the manufacturing process that may come into contact with the product that are the lowest risk scenarios. Scenarios that are considered to be the lowest risk are situations in which no mitigation strategies exist or cannot be implemented within reason.

## 6. PROCESS FLOW DIAGRAM:

Sodium Hydroxide Solution Manufacturing Process Flow Diagram



## 7. PROFILE:

- 7.1. Manufacturing Location:
  - 7.1.1. Bangor, Pa Facility
- 7.2. Applicable Product Codes:
  - 7.2.1. NH41XX and lower compliance grades
- 7.3. TUPPs originating from product contacting surfaces in the manufacturing process and packaging are detailed in the following Tables:

<b>Originating from the Manufacturing process</b>				
<b>Identity</b>	<b>Characterization</b>	<b>Origin</b>	<b>How Removed</b>	<b>How Prevented</b>
Polypropylene	Blue Plastic, black plastic	Centrifugal Pump, Fill Valve, pipe fittings, Purification	10-Micron Filter 5-Micron Filter	Pre-Process Inspection, Preventative Maintenance,
Proprietary	Proprietary	Purification	10-Micron Filter 5-Micron Filter	Pre-Process Inspection, Preventative Maintenance,
PVC	White, Gray, Opaque plastic	Storage Tanks, piping	10-Micron Filter 5-Micron Filter	Pre-Process Inspection, Preventative Maintenance
Silicone	Orange or white elastomer	Process Tank manway o-ring	10-Micron Filter 5-Micron Filter	Pre-Process Inspection, Preventative Maintenance
Stainless Steel 316	Metallic shaving	Centrifugal Pump, Purification Equipment, Process Pipes, Process Tanks, Tank Agitators	10-Micron Filter 5-Micron Filter	Pre-Process Inspection, Preventative Maintenance
HDLPE	Off-White, White, Opaque plastic	Storage Tanks	10-Micron Filter 5-Micron Filter	Pre-Process Inspection, Preventative Maintenance
U.H.M.W. PE	Clear Plastic	Chemical Hoses	10-Micron Filter 5-Micron Filter	Pre-Process Inspection, Preventative Maintenance
CPVC	Gray, Opaque plastic	Storage Tanks	10-Micron Filter 5-Micron Filter	Pre-Process Inspection, Preventative Maintenance
EPDM	Black Elastomer	Storage Tanks, gaskets, Hand Valves	10-Micron Filter 5-Micron Filter	Pre-Process Inspection, Preventative Maintenance
PTFE	White Plastic	Centrifugal Pump, Hose and Piping Gaskets, Hand Valves	10-Micron Filter 5-Micron Filter	Pre-Process Inspection, Preventative Maintenance
FEP	Clear Plastic	Tank Agitator O-ring, fill valve o-ring	10-Micron Filter 5-Micron Filter	Pre-Process Inspection, Preventative Maintenance
Silicon Carbide	Metallic Ceramic	Tank Agitators	10-Micron Filter 5-Micron Filter	Pre-Process Inspection, Preventative Maintenance

<b>Originating from the Manufacturing process</b>				
<b>Identity</b>	<b>Characterization</b>	<b>Origin</b>	<b>How Removed</b>	<b>How Prevented</b>
Zirconium Oxide	Off White Ceramic	Tank Agitator	10-Micron Filter 5-Micron Filter	Pre-Process Inspection, Preventative Maintenance
Viton	Black or Brown Elastomer	Centrifugal Pump	10-Micron Filter 5-Micron Filter	Pre-Process Inspection, Preventative Maintenance
Buna N	Black Elastomer	Filter Housing O-ring	10-Micron Filter 5-Micron Filter	Pre-Process Inspection, Preventative Maintenance
Ceramic	Off White Ceramic	Centrifugal Pump	10-Micron Filter 5-Micron Filter	Pre-Process Inspection, Preventative Maintenance
Kalrez	Black or Brown Elastomer	Centrifugal Pump	10-Micron Filter 5-Micron Filter	Pre-Process Inspection, Preventative Maintenance

7.4. TUPPs originating from product contacting surfaces of the packaging components:

7.4.1. The following TUPPs are dependent on the packaging type.

<b>Originating from the Packaging Process</b>			
<b>Identity</b>	<b>Characterization</b>	<b>Origin</b>	<b>How Prevented</b>
HDPE	White/opaque plastic	Finished Good Drum	Inspection