

**PACKAGING SPECIFICATION OF SULFOBUTYL-ETHER- β -CYCLODEXTRIN
SODIUM SALT (SBECD, DEXOLVE™) BULK MATERIAL**

Primary Packaging Material: Polyethylene bag (sterile, gamma-irradiated)

Dimensions: thickness: 0.100 mm; 40 x 90 cm

Tests and methods	Requirements
Appearance, packaging (visual)	Colorless bag, free from visible mechanical contaminations, the packaging is free from any observable damage
Identification	The received material complies with CycloLab Purchase Order
Size (visual)	Declared dimensions \pm 2 %

Storage: at room temperature; Shelf life: 5 years (the expiration date of the packaging material is determined based on the stability test)

Secondary Packaging Material: heat-sealed, three-layered foil bag two pressure relief valves

Material: inner layer: PE (60 μ m), middle layer: aluminum (7 μ m), outer layer: PET (12 μ m)

Dimensions: thickness: 0.079 mm; 75 x 45 cm

Tests and methods	Requirements
Appearance, packaging (visual)	Free from visible mechanical contaminations, the packaging is free from any observable damage
Identification	The received material complies with CycloLab Purchase Order
Size (visual)	Declared dimensions \pm 2 %

Storage: at room temperature; Shelf life: 5 years (the expiration date of the packaging material is determined based on the stability test)

Tertiary Packaging Materials:

HDPE blue drum with locking clamp (60 L)

Material: HDPE granules; Clamp material: Steel

Dimensions: 60 x 38 cm; Total weight: 1.9 kg

Tests and methods	Requirements
Appearance (visual)	Free from visible mechanical contaminations and damages
Closure (visual)	Presence of sealing material

Storage: at room temperature.

Fiber drums with locking clamp (Small, 15 L)

Material: fiber; Clamp material: Steel

Dimensions: 31 x 20.5 cm Total weight: 2.2 kg

Tests and methods	Requirements
Appearance (visual)	Free from visible mechanical contaminations and damages
Closure (visual)	Presence of sealing material

Storage: at room temperature.

Fiber drums with locking clamp (Medium, 40 L)

Material: fiber; Clamp material: Steel

Dimensions: 40 x 34.5 cm Total weight: 3.0 kg

Tests and methods	Requirements
Appearance (visual)	Free from visible mechanical contaminations and damages
Closure (visual)	Presence of sealing material

Storage: at room temperature.

Fiber drums with locking clamp (Large, 100 L)

Material: fiber; Clamp material: Steel

Dimensions: 40 x 82.5 cm Total weight: 4.3 kg

Tests and methods	Requirements
Appearance (visual)	Free from visible mechanical contaminations and damages
Closure (visual)	Presence of sealing material

Storage: at room temperature.

Locking clamp (lead/seal): Mini Cable Lock Premium 1,5 mm, White with ADD with 30 cm wire, Metal or equivalent seal.

Cable tie: natural, white or black colored plastic minimum 100 mm long cable tie.

Desiccant: Active silica gel pad

Quality: meets the FDA requirements

Dimensions: 110 x 110 mm, weight: 100 g, 25 g

Tests and methods	Requirements
LOD (CoA of the manufacturer)	NMT 4.0 %
Water absorption capacity (RH 50%) (CoA of the manufacturer)	≥ 25.0 %

Storage: at room temperature, in tightly closed container

Packaging instructions: The dried SBECD bulk powder must be filled into a gamma sterilized PE bag that is twist-tied and quick shut with cable tie as the last step of the manufacturing. This PE bag is placed into the Triplex foil bag (secondary packaging material) with silica gel desiccant that is then heat sealed and labelled.

The packaged product is then transferred to HDPE containers or fiber drums as tertiary packaging material, and then secured with tamper evident seals.

Adequate labels should be placed on the inner PE bag, Triplex foil bag and HDPE drums for identification.



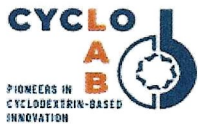
**CYCLOLAB
CYCLODEXTRIN RESEARCH & DEVELOPMENT
LABORATORY LTD.**

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ISO 9001



Blank packaging label (small):

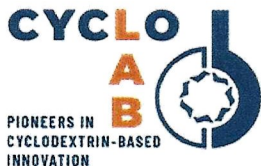


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Product name: Sulfobutyl-ether- β -cyclodextrin sodium salt (SBECD)
Quality: USP NF and EP (for manufacturing of injectable dosage forms)
Batch No.: **pack**
Net weight: **kg**
Preserve in well-closed containers, store at room temperature.
Protect from moisture.

Expiry date:

Blank packaging label (big):



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Product name:	<u>Sulfobutyl-ether-β-cyclodextrin sodium salt</u>	drum
Batch No.:		
PO-No.:		
Gross weight:	kg	
Net weight: kg	
Storage:	Preserve in well-closed containers, store at room temperature. Protect from moisture.	
Expiry date:		

Photos:



[Signature] 25 September, 2023
QC / date

[Signature] 25 September, 2023
QA / date

Change

- v02: "complies with EP and FDA regulation" was deleted, new tertiary packaging option: fiber drum, secondary packaging was modified with pressure relief
- v03: one PE bag option, modified PE bag specification (weight criteria was deleted)
- v04: the pictures were changed
- v05: supplemented with cable tie and locking clamp
- v06: updated the specification, corrected expiry date, addition of dimensions and total weights