

PRODUCT SPECIFICATION	
Product: 6-Deoxy-6-thio-heptakis(6-deoxy-6-(2-carboxyethyl) thio)-gamma-cyclodextrin partly sodium salt (Mono-SH-SGM) Molecular formula: $C_{69}H_{108-n}Na_nO_{46}S_8$ Formula weight: $1930 + n \cdot 22$ Quality: analytical standard	Version: 01 Code: Rel_SGM_CY_3222_v01

Prepared by (QC)/date:	Revised by (QA)/date:	Approved by (QA)/date:
<i>Okle Ferenc</i> 19 October 2022	<i>Imol Szilvia</i> 19 October 2022	<i>Okle Ferenc</i> 19 October 2022

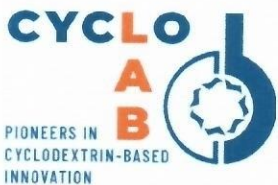
Tests and methods	Requirements
Appearance/ visual#	white or off-white powder
Identification 1 / LC-MS (EP 2.2.29., 2.2.43)	conforms to theoretical mass
Identification 2 / NMR (EP 2.2.33)	conforms to theoretical structure
Identification 3 / IR (EP 2.2.24)	conforms to standard
Purity# ¹ / HPLC (EP 2.2.29)	> 90.0 area %
Other cyclodextrin-related impurities# ¹ / HPLC (EP 2.2.29)	< 10.0 area %
Sodium formate content / CE (EP 2.2.47)	< 3.0 w/w %
Sodium content ² / CE (EP 2.2.47)	< 10.0 w/w %
Residual solvents / TGM-MS (EP 2.2.34, 2.2.43)	< 10.0 w/w %
Purity calculated ³	to be reported

tests to extend expiry

1 HPLC analysis to be carried out on an Agilent Poroshell column with H_3PO_4 / NH_3 buffer system at pH=2.6 and UV-Vis detection

2 The compound is supplied in slightly acidic form for stability reasons; the actual molar sodium content (n) is indicated on the Certificate of Analysis of each batch.

3 Calculated purity (w/w%) = ((100 (w/w%) - Sodium formate content (w/w%) - Residual solvents (w/w%))*Purity (area%))/100



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Notes: the compound is a single isomer.

Comments: only for reagent and laboratory purposes, not for human use.

Storage: in deep freezer, under inert atmosphere, in tightly closed container.

Retest date: 12 months from date of qualification.

Version No:	Short description of change
01	First version