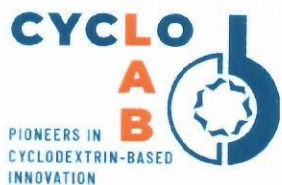


PRODUCT SPECIFICATION	
Product: 6-Deoxy-6-chloro-heptakis(6-deoxy-6-(2-carboxyethyl)thio)-gamma-cyclodextrin partly sodium salt (Mono-Cl-SGM) Molecular formula: $C_{69}H_{107-n}ClNa_nO_{46}S_7$ Formula weight: $1932.5 + n \cdot 22$ Quality: analytical standard	Version: 01 Code: Rel_SGM_CY_3208_v01

Prepared by (QC)/date:	Revised by (QA)/date:	Approved by (QA)/date:
<i>Oleksa Fucini</i> 29, September 2022	<i>Orsolya Nádai</i> 29, September 2022	<i>[Signature]</i> 29 September 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 ² / CE (EP 2.2.47)	< 3.0 w/w%
Sodium content / 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%) = $((100 \text{ (w/w\%)} - \text{Sodium formate content (w/w\%)} - \text{Residual solvents (w/w\%)}) \cdot \text{Purity (area\%)}) /$



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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

<i>Version No.</i>	<i>Short description of change</i>
01	First version