## **Certificate of Analysis**



## Product Identification

11065300 Cefuroxime sodium

CA 5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 3-[[(aminocarbonyl)oxy]methyl]-7-[[(2E)-Lot Number 992377

IUPAC Sodium (6R-(6alpha,7beta(Z)))-3-(((aminocarbonyl)oxy)methyl)-7-(2-

Store at 4 °C ±4 °C

Expiry Date 10,12,2021

Formula C16H15N4NaO8S

Mol.Weight 446.37 CAS No. 56238-63-2

Please note: The expiry date is valid under recommended storage conditions only.

Toxicological Data

Phase crystalline solid Color yellowish Melt.Range

Physical Data

Vapour pressure N/A at °C Solubility in water N/A g/l at °C

Boiling Range (lit.)

R Code 42/43

S Code 22-36/37-45

LD50 (Rats female/male in mg/kg) >10000

Analytical Data

Detection: HPLC/DAD

Method Details:

Column:

Ini.-Vol.: 10.00 µl Flow: 1.0 ml/min Ret.-Time: 9.82 min.

Identity: IR, UV, RT, EA, NMR

Column: Nucleodur 100 C8, 3 µm, 250 x 4 mm Comment

Purity was determined by elemental analysis.

Eluent: 90% Sodium acetate (0.68 g) in 1 L w ater (pH 3.4 w ith acetic acid) and 11 mL acetonitrile 10% acetonitrile

Water Content 2.4 % Determined by Karl-Fischer Titration Det. Purity 97.0 % Tolerance/Uncertainty +/- 2.0 %

The uncertainty/tolerance of this standard is calculated in accordance with the EURACHEWCITAC Guide - Quantifying Uncertainty in Analytical Measurement - Second Edition. The uncertainty given is the expanded combined uncertainty and represents an estimated standard deviation equal to the positive square root of the total variance of the uncertainty of components. The expanded uncertainty is U which is Uc(y)\*K, where K is the coverage factor at the 95% confidence level (K=2). The expanded uncertainty is based on the combination of uncertainties associated with each individual operation involved in the preparation of this product.

Certified on 10.12.2018

by M. Beck

plan

The Laboratory LGC Labor GmbH is accreditated by DAkkS as indicated by the Accreditation Number D-RM-19883-01 & D-PL-19883-01 has shown competence based on ISO Guide 34:2009 with relevant parts of DIN EN ISO/IEC 17025:2005 for production of certified reference materials in form of organic pure substances and in form of single and multi-component solutions organic pure substances.

23/11/15/

Data file:

11065300-03-r001.dx

Sample name:

81122WA 992377

Instrument:
Sequence Name:

DAD3

22112018-SE

lnj. volume [μl]:

10.0

Injection date:

11/22/2018 9:24:54 AM

Acq. method:

19K\_BD\_20MIN\_S2.amx

Location:

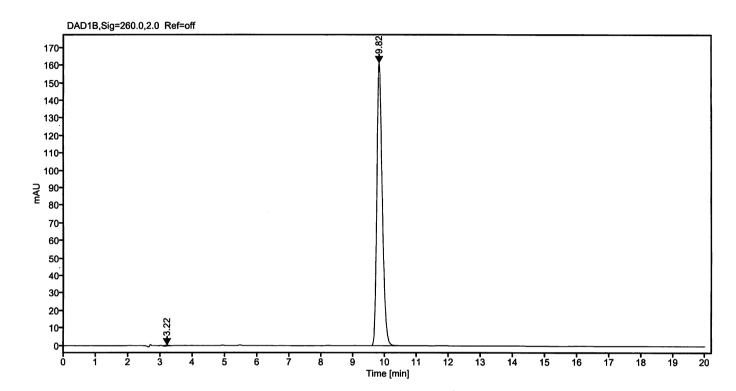
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**Sample Description** 

Cefuroxime sodium

Column: Nucleodur 100 C8, 3 µm, 250 x 4 mm

Eluent: Sodium acetate (0.68 g) in 1 L water (pH 3.4 with Acetic acid) and 11 mL Acetonitrile



Signal:	DAD1B,Sig=260.0,2.0 Ref=off				
Nr.	RT [min]	Area	Height	Area%	
1	3.22	5.31577	0.53	0.28	
2	9.82	1922.07701	161.45	99.72	
	Sum	1927.39			

J. Bed