SIGMA-ALDRICH®

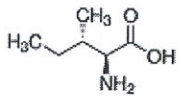
sigma-aldrich.com

3050 Spruce Street, Saint Louis, MO 63103, USA
Website: www.sigmaaldrich.com
Email USA: techserv@sial.com
Outside USA: eurtechserv@sial.com

Certificate of Analysis

Product Name:

L-Isoleucine - from non-animal source, meets EP, JP, USP testing specifications, suitable for cell culture, 98.5-101.0%



Product Number:	**I7403**
Batch Number:	**SLBZ2358**
Brand:	SIGMA
CAS Number:	73-32-5
MDL Number:	MFCD00064222
Formula:	C6H13NO2
Formula Weight:	131.17 g/mol
Quality Release Date:	19 OCT 2018
Recommended Retest Date:	OCT 2022

Test	Specification	Result
Origin	Non-Animal Source	Conforms
Appearance (Color)	White	White
Appearance (Form)	Powder or Crystals	Powder
Solubility (Color)	Colorless	Colorless
Solubility (Turbidity) 0.5 g to 10 ml of 1M HCl	Clear	Clear
Identity by IR	Conforms to Structure	Conforms
Specific Rotation EP/JP at 20 deg C; c = 4 in 6 M HCl	40.0 - 41.5 °	41.1 °
Specific Rotation USP at 25 deg C; c = 4 in 6 M HCl	38.9 - 41.8 °	40.7 °
Chloride Content < or = 0.020%	Conforms	Conforms
Ammonium < or = 0.02%	Conforms	Conforms
Sulfate < or = 0.020%	Conforms	Conforms
Iron (Fe) < or = 10 ppm	Conforms	Conforms
Heavy Metals < or = 10 ppm	Conforms	Conforms
Arsenic (As) < or = 1 ppm	Conforms	Conforms

REPUBLICA MOLDOVA, mun. CHISINAU S.R.L. «MIC-TAN»

Sigma-Aldrich warrants, that at the time of the quality release or subsequent retest date this product conformed to the information contained in this publication. The current Specification sheet may be available at Sigma-Aldrich.com. For further inquiries, please contact Technical Service. Purchaser must determine the suitability of the product for its particular use. See reverse side of invoice or packing slip for additional terms and conditions of sale.

Version Number: 1

Digitally signed by Michiciuc Gheorghe
Date: 2019.06.11 11:36:55 EEST
Reason: MoldSign Signature
Location: Moldova

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Product Number: I7403
Batch Number: SLBZ2358

Test	Specification	Result
Loss on Drying	≤ 0.20 %	0.02 %
Residue on ignition (Ash)	≤ 0.10 %	0.03 %
Residual Solvents USP 467	Meets Requirements	No Residual Solvents are Present
Ninhydrin-Positive Substances	Conforms	Conforms
pH USP; 1.0 % in H2O	5.5 - 7.0	6.1
pH by EP/JP; 1.0 % in H2O	5.5 - 6.5	6.2
Assay dry basis	98.5 - 101.0 %	99.7 %
Endotoxin Assay	≤ 1 EU/mg	0 EU/mg
Cell Culture Test	Pass	Pass
Cell Line	Attached Cell Line	CHO
Cell Line	Attached Cell Line	BHK
Cell Line	Attached Cell Line	VERO
Note Meets USP 40, EP 8.8, and JP 17 testing specifications	----------	----------

Rodney Burbach, Manager
Analytical Services
St. Louis, Missouri US

Version Number: 1

Honeywell

Honeywell Laborchemikalien GmbH, Wunstorfer Str. 40, 30926 Seelze Germany
Tel.: 049(0)5137-999-0
SeelzeRC.support@honeywell.com

Certificate of Analysis

Product Name:	Ethanol absolute, reag. ISO, reag. Ph. Eur., >= 99.8% (v/v) GC, liquid clear, colorless
Product Number:	32205
Batch Number:	SZBG0060V
Brand:	Sigma-Aldrich
CAS Number:	64-17-5
Formula:	CH_3CH_2OH
Formula Weight:	46.07

TEST	SPECIFICATION	RESULT
appearance	complying	complying
assay (GC)	≥ 99.8	99.9 Vol.%
boiling range	–	78 - 79 °C
density (D 20/20)	0.790-0.791	0.7908
refractive index (n 20/D)	1.3612-1.3618	1.3613
non-volatile matter	≤ 0.001	< 0.001 %
water (Karl Fischer)	≤ 0.2	0.03 %
free acid (as CH3COOH)	≤ 0.0005	< 0.0005 %
free alkali (as NH3)	≤ 0.0001	< 0.0001 %
aluminium (Al)	≤ 0.00005	< 0.00005 %
boron (B)	≤ 0.000002	< 0.000002 %
barium (Ba)	≤ 0.00001	< 0.00001 %
calcium (Ca)	≤ 0.00005	< 0.00005 %
cadmium (Cd)	≤ 0.000005	< 0.000005 %
cobalt (Co)	≤ 0.000002	< 0.000002 %
chromium (Cr)	≤ 0.000002	< 0.000002 %
copper (Cu)	≤ 0.000002	< 0.000002 %
iron (Fe)	≤ 0.00001	< 0.00001 %
magnesium (Mg)	≤ 0.00001	< 0.00001 %
manganese (Mn)	≤ 0.000002	< 0.000002 %
nickel (Ni)	≤ 0.000002	< 0.000002 %
lead (Pb)	≤ 0.00001	< 0.00001 %
tin (Sn)	≤ 0.00001	< 0.00001 %
zinc (Zn)	≤ 0.00001	< 0.00001 %

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heavy metals (as Pb)	≤ 0.0001	< 0.0001 %
acetone (GC)	≤ 0.001	< 0.001 %
aldehydes (as CH3CHO)	≤ 0.001	< 0.001 %
iso-amyl alcohol (GC)	≤ 0.05	< 0.05 %
carbonyl compounds (as CO)	≤ 0.003	< 0.003 %
furfural	complying	complying
methanol (GC)	≤ 200	< 200 Vol.pp
2-propanol (GC)	≤ 0.003	< 0.003 %
higher alcohols (GC)	≤ 0.01	< 0.01 %
volatile impurities (GC)	complying	complying
KMnO4 red. matter (as O)	≤ 0.0003	< 0.0003 %
reaction against H2SO4	complying	complying
UV-absorption	complying	complying
APHA	≤ 10	< 10

Identity, assay and impurities are complying to the monographs of the above mentioned pharmacopeias/codices.

Production Date	06.Jan.16
Rec. Retest Date	13.Jun.20
QC Release Date	15.Jan.16

Dr. Burkhard Vehre
Quality Management
Honeywell Laborchemikalien GmbH, Seelze

REPUBLICA MOLDOVA, mun. CHISINAU S.R.L. «MIC-TAN» IDNO 1002600038282 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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Certificate of Analysis

Product Name:	AMMONIUM IRON(II) SULFATE HEXAHYDRATE BioUltra, >= 99.0 % RT
Product Number:	09719
Batch Number:	BCBW6167
Brand:	Sigma-Aldrich
CAS Number:	7783-85-9
Formula:	$(NH_4)_2Fe(SO_4)_2 * 6H_2O$
Formula Weight:	392.14
Quality Release Date:	06 MAR 2018
Recommended Retest Date:	JAN 2024

TEST	SPECIFICATION	RESULT
APPEARANCE (COLOR)	WHITE TO FAINTLY GREEN OR FAINTLY GREENISH-BLUE	FAINT GREEN
APPEARANCE (FORM)	POWDER OR CRYSTALS	CRYSTALS
REDOX TITRATION	99.0 - 101.0 %	100.1 %
REDOXTITRATION (METHOD)	PERMANGANATE TITRATION	PERMANGANATE TITRATION
METAL TRACE ANALYSIS (ICP)	CORRESPONDS TO REQUIREMENTS	PASSED
CADMIUM (ICP)	≤ 5 MG/KG	< 5 MG/KG
COBALT (ICP)	≤ 50 MG/KG	< 50 MG/KG
CHROMIUM (ICP)	≤ 50 MG/KG	< 50 MG/KG
COPPER (ICP)	≤ 5 MG/KG	< 5 MG/KG
POTASSIUM (ICP)	≤ 50 MG/KG	< 50 MG/KG
MAGNESIUM (ICP)	≤ 100 MG/KG	< 100 MG/KG
MANGANESE (ICP)	≤ 500 MG/KG	< 500 MG/KG
SODIUM (ICP)	≤ 50 MG/KG	< 50 MG/KG
NICKEL (ICP)	≤ 100 MG/KG	< 100 MG/KG
LEAD (ICP)	≤ 5 MG/KG	< 5 MG/KG
STRONTIUM (ICP)	≤ 5 MG/KG	< 5 MG/KG
ZINC (ICP)	≤ 5 MG/KG	< 5 MG/KG
CHLORIDE (CL)	≤ 10 MG/KG	< 10 MG/KG
PHOSPHATE (PO4)	≤ 20 MG/KG	< 20 MG/KG
FERRIC IRON	≤ 50 MG/KG	< 50MG/KG
SOLUBILITY (METHOD)	WATER 0.5M	WATER 0.5M
APPEARANCE (SOLUTION)	CLEAR FAINTLY GREEN-YELLOW TO FAINTLY GREEN-BLUE	CLEAR FAINTLY GREEN-YELLOW

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PH (SOLUTION)	2.5 - 4.0	3.4
RESIDUE (FILTER TEST)	NO RESIDUE	NO RESIDUE

Dr. Reinhold Schwenninger
Quality Assurance
Buchs, Switzerland

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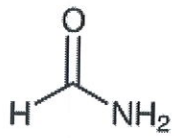
Certificate of Analysis

Product Name:
Formamide – puriss. p.a., ACS reagent, ≥99.5% (GC/T)

Product Number:	**47670**
Batch Number:	**WXBC9423V**
Brand:	SIGALD
CAS Number:	75-12-7
Formula:	CH3NO
Formula Weight:	45,04 g/mol
Quality Release Date:	12 FEB 2019
Recommended Retest Date:	MAY 2021



Test	Specification	Result
Appearance (Colour)	Colorless	Colorless
Appearance (Form)	Liquid	Liquid
Density D20/4	1.131 - 1.133	1.133
Color Test	≤ 10 APHA	< 10 APHA
Purity (GC)	≥ 99.5 %	99.7 %
Refractive index at 20 ° C	1.446 - 1.448	1.448
Freezing Point	2.0 - 3.0 ℃	2.0 ℃
Water (by Karl Fischer)	≤ 0.1 %	0.0 %
Infrared spectrum	Conforms to Structure	Conforms
Trace Analysis (Additional test)	Corresponds to Requirements	Corresponds
Free Acid (as HCOOH) = < 0.02%,		
Miscibility (in H2O,IN EtOH)		
In accordance		
ACS specifications	Corresponds to Requirements	Corresponds
10th Edition		
Trace Metal Analysis	Pass	Pass
Calcium (Ca)	≤ 5 ppm	1 ppm
Cadmium (Cd)	≤ 1 ppm	< 1 ppm
Cobalt (Co)	≤ 1 ppm	< 1 ppm
Chromium (Cr)	≤ 1 ppm	< 1 ppm
Copper (Cu)	≤ 1 ppm	< 1 ppm
Iron (Fe)	≤ 1 ppm	< 1 ppm
Potassium (K)	≤ 20 ppm	< 1 ppm

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Version Number: 1

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Product Number: 47670
Batch Number: WXBC9423V

Test	Specification	Result
Magnesium (Mg)	≤ 1 ppm	< 1 ppm
Manganese (Mn)	≤ 1 ppm	< 1 ppm
Sodium (Na)	≤ 20 ppm	3 ppm
Nickel (Ni)	≤ 1 ppm	< 1 ppm
Lead (Pb)	≤ 1 ppm	< 1 ppm
Zinc (Zn)	≤ 1 ppm	< 1 ppm

Steven Chen, Manager
Quality Control
Wuxi, China CN

Version Number: 1

SIGMA-ALDRICH®

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Certificate of Analysis

Product Name:	ACETIC ANHYDRIDE puriss. p.a., ACS reagent, reag. ISO, reag. Ph. Eur., >= 99 % GC
Product Number:	33214
Batch Number:	STBG7804
Brand:	Sigma-Aldrich
CAS Number:	108-24-7
Formula:	$(CH_3CO)_2O$
Formula Weight:	102.09
Quality Release Date:	02 JAN 2017
Recommended Retest Date:	JUN 2020

TEST	SPECIFICATION	RESULT
PURITY (GC AREA %)	≥ 99 %	99 %
DENSITY D20/4	1.079 - 1.082	1.081
BOILING POINT	CA 139 DEG C	136 - 138 DEG C
RESIDUE (EVAPORATION)	≤ 0.003 %	< 0.003%
REDUCING SUBSTANCES	≤ 0.01 %	< 0.01 %
HEAVY METALS	≤ 0.0002 % (AS PB)	< 0.0002 %
ALUMINIUM	≤ 0.5 PPM	< 0.5 PPM
BARIUM	≤ 0.1 PPM	< 0.1 PPM
BISMUTH	≤ 0.1 PPM	< 0.1 PPM
BORON	≤ 0.02 PPM	< 0.02 PPM
CALCIUM	≤ 0.5 PPM	< 0.5 PPM
CADMIUM	≤ 0.05 PPM	< 0.05 PPM
COBALT	≤ 0.02 PPM	< 0.02 PPM
CHROMIUM	≤ 0.05 PPM	< 0.05 PPM
COPPER	≤ 0.02 PPM	< 0.02 PPM
IRON	≤ 0.1 PPM	< 0.1 PPM
POTASSIUM	≤ 0.5 PPM	< 0.5 PPM
LITHIUM	≤ 0.1 PPM	< 0.1 PPM
MAGNESIUM	≤ 0.1 PPM	< 0.1 PPM
MANGANESE	≤ 0.02 PPM	< 0.02 PPM
MOLYBDENUM	≤ 0.1 PPM	< 0.1 PPM
SODIUM	≤ 0.5 PPM	< 0.5 PPM
NICKEL	≤ 0.02 PPM	< 0.02 PPM
LEAD	≤ 0.1 PPM	< 0.1 PPM

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TIN	≤ 0.1 PPM	< 0.1 PPM
STRONTIUM	≤ 0.1 PPM	< 0.1 PPM
ZINC	≤ 0.2 PPM	< 0.2 PPM
CHLORIDE (CL)	≤ 0.0002 %	< 0.0002 %
PHOSPHATE (PO4)	≤ 0.001 %	< 0.001 %
SULFATE (SO4)	≤ 0.0005 %	< 0.0005 %
SUBSTANCES DARK BY H2SO4	COMPLYING	COMPLYING

Claudia Mayer
Manager Quality Control
Steinheim, Germany

TraceCERT®
Traceable Certified Reference Materials

SIGMA-ALDRICH®

Certificate

Produced in double accredited laboratory fulfilling ISO/IEC 17025 and ISO 17034

This certificate is designed in accordance with ISO Guide 31 [1].

Object of certification:	**Nickel Standard for AAS**
Product No.:	**42242**
Lot:	**BCBW8384**
Composition:	Nickel metal (pure material) in 2% HNO_3 (prepared with HNO_3 suitable for trace analysis and high-purity water, 18.2 MΩ·cm, 0.22 µm filtered).
Density at 20°C:	ρ = 1012 kg m^{-3} $u_c(\rho)$ = 0.5 kg m^{-3}
Intended use:	Calibration of AAS, ICP, spectrophotometry or any other analytical technique.
Storing and handling:	This reference material shall be stored between 5 °C and 30 °C. Before every use of the material the bottle must be shaken well and its temperature has to be 20°C. If storage of a partially used bottle is necessary, the cap should be tightly sealed and the bottle should be stored at reduced temperature (e.g. refrigerator) to minimize transpiration rate.
Expiry date:	**APR 2021**
Certificate issue date:	01 JUN 2018
Certification version:	01
Bottle opening date:	

Certified value traceable to SI unit kg and uncertainty according to ISO Guide 35 [2] and Eurachem/CITAC Guide [3]		
Constituent	Certified value at 20°C and expanded uncertainty [$U = k u_c$; $k = 2$]	
Nickel	**989 mg kg^{-1} ± 4 mg kg^{-1}**	**1'000 mg L^{-1} ± 4 mg L^{-1}**

1. Concept of Certification and Traceability Statement

To guarantee top reliability of the values for this *Trace***CERT®** certified reference material three independent procedures were followed. The values have to agree in the range of their uncertainties, but the impurity corrected value from the gravimetric preparation has been chosen as certified value [4]:

1. Gravimetric preparation using pure materials is a practical realization of concentration units, through conversion of masses and mole fraction to mass fraction [4]. If the purity of the materials is demonstrated and if contamination and loss of material is strictly prevented this approach allows highest accuracy and small uncertainties. The certified value of *Trace***CERT®** reference materials is based on this approach and directly traceable to the SI unit kilogram.

   Therefore comprehensively characterized materials of highest purity are used (see paragraph 2). All balances are certified by DKD and calibrated with OIML Class E2 (up to 12 kg) and F2 (up to 64 kg) weights. The bulk solution was homogenized by overhead tumbling in a PVDF container for at least 6 hours. A peristaltic pump with perfluorinated polymer tubings was used for bottling.

2. The starting material is measured against a certified reference material (e.g. NIST or BAM) followed by gravimetric preparation using balances calibrated with SI-traceable weights. Consequently the value calculated by this unbroken chain of comparisons is traceable to the reference to which the starting material is compared.

3. Whenever applicable the bottled *Trace***CERT®** calibration solution is compared to a second reference which is independent from the first reference.

Sigma-Aldrich Production GmbH, Industriestrasse 25, 9471 Buchs/Switzerland,
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SIGMA-ALDRICH®

2. Purity of Starting Materials

For high purity materials (P >99.9 %) the most appropriate way of purity determination is to quantify the impurities (w_i) and to subtract the sum from 100 %. Impurities below the detection limit are considered with a contribution of half of the detection limit (DL_j).

$$P = 100\% - \sum_i w_i - \sum_j \left(\frac{DL_j}{2} \right)$$

Water containing materials were dried to absolute dryness by individual drying conditions (up to 600°C). When drying is impossible due to decomposition water was determined by high-precision KF-titration at Sigma-Aldrich.
High purity water (18.2 MΩ·cm; 0.22 µm filtered, all metallic traces at ng kg^{-1}-level) and high purity acid for trace analysis were used for preparation.

3. Traceability Measurements

Only internationally accepted reference materials e.g. from NIST (USA) or BAM (Germany) have been carefully selected to provide the basis for traceability to the SI unit mole. When no such reference is available, an elemental metal or an adequate salt of highest available purity is used to confirm traceability to this pure material (and therefore to the SI unit kg).
To underpin the certified gravimetric value all traceability measurements are performed with the most accurate and precise analytical technique available. Therefore titrimetry measurement series are applied whenever possible (corrected for trace impurities). When no titrimetric technique is available, the traceability measurements are performed with another analytical technique, e.g. ICP-OES or AAS.

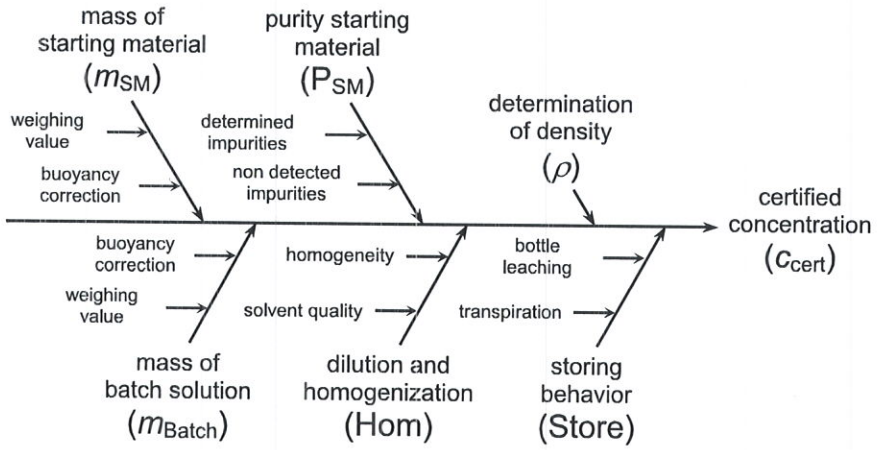
Reference and applied technique used for traceability measurements of the

starting material: NIST SRM 728 / complexometric titration

bottled solution: BAM 365 / complexometric titration

4. Uncertainty Evaluation

All uncertainties are calculated according to Eurachem/CITAC Guide [3] and reported as combined expanded uncertainties at the 95 % confidence level. For gravimetric preparation the uncertainty contributions are illustrated by the following cause-effect diagram [5]:



Typical contributions:

$u(m_{SM})$	< 0.01 %
$u(m_{Batch})$	< 0.01 %
$u(P_{SM})$	< 0.05%
u(Hom)	< 0.03 %
u(Store)	< 0.17%
$u(\rho)$	< 0.05 %

Combined uncertainty [6]:

$u_c(c_{cert})$ < 0.2%

Expanded uncertainty:

$U(c_{cert})$ < 0.4%

CRM operations: S. Matt

S.Matt

Approving Officer:

P. Zell, Ph.D.

ISO 17034 SRMS 0001 | **ISO/IEC 17025** STS 0490 | **ISO 9001** 005356 QM08

[1] ISO Guide 31:2015, "Reference materials - Contents of certificates, labels and accompanying documentation"
[2] ISO Guide 35:2017, "Reference materials – Guidance for characterization and assessment of homogeneity and stability"
[3] Eurachem/CITAC Guide, 3rd Ed. (2012), "Quantifying uncertainty in analytical measurement"
[4] Eurachem/CITAC Guide, 1st Ed. (2003) "Traceability in chemical measurement"
[5] Reichmuth, A., Wunderli, S., Weber, M., Meyer, V. R. (2004), "The uncertainty of weighing data obtained with electronic analytical balances", Microchimica Acta 148: 133-141.
[6] Calculated by combination of the squared contribution values

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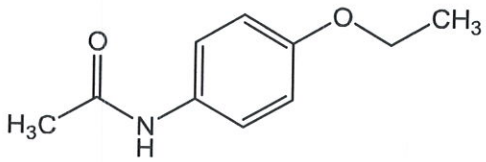
Certificate of Analysis

ISO 17034
ANAB Cert# AR-1470

ISO/IEC 17025
ANAB Cert# AT-1467

PHENACETIN
MELTING POINT STANDARD
CERTIFIED REFERENCE MATERIAL



NOMINAL PACKAGE SIZE: 1g

CATALOG #: PHR1094 **LOT #:** LRAA8978

CERTIFICATE VERSION: LRAA8978.5 **ISSUE DATE:** 27 March 2019

Note: Certificates may be updated due to Pharmacopeial Lot changes or the availability of new data. Check our website at: www.sigma-aldrich.com *for the most current version.*

CRM EXPIRATION: 31 December 2020 (Proper Storage and Handling Required).

RECEIPT DATE: _____

Note: this space is provided for convenience only and its use is not required.

STORAGE: Store in a Refrigerator, keep container tightly closed. Attachment of a 20 mm aluminum crimp seal recommended for unused portions.

CHEMICAL FORMULA: $C_{10}H_{13}NO_2$ **MW:** 179.22

PHYSICAL DESCRIPTION: White powder in amber vial **CAS #:** 62-44-2

HAZARDS: Read Safety Data Sheet before using. All chemical reference materials should be considered potentially hazardous and should be used only by qualified laboratory personnel.

INSTRUCTIONS FOR USE: Dry at 105°C for 4 hours prior to use. The internal pressure of the container may be slightly different from the atmospheric pressure at the user's location. Open slowly and carefully to avoid dispersion of the material. This material is intended for Laboratory Use only. Not for drug, household or other uses.

SIGMA-ALDRICH

CERTIFIED MELTING RANGE/POINT
(dried basis)

METHOD: All samples were dried at 105°C for 4 hours prior to use. The melting range/melting point of the Phenacetin Melting Point Standard was determined concomitantly with the melting range/melting point of the USP Phenacetin Melting Point Standard using the capillary method. This method demonstrates direct traceability to the USP Reference Standard.

Reference: USP <741>
Instrument: Mettler Toledo FP900 Thermosystem with FP81 Measuring Cell

Temperature Program: 130 to 141.0°C at 1.0°C/min

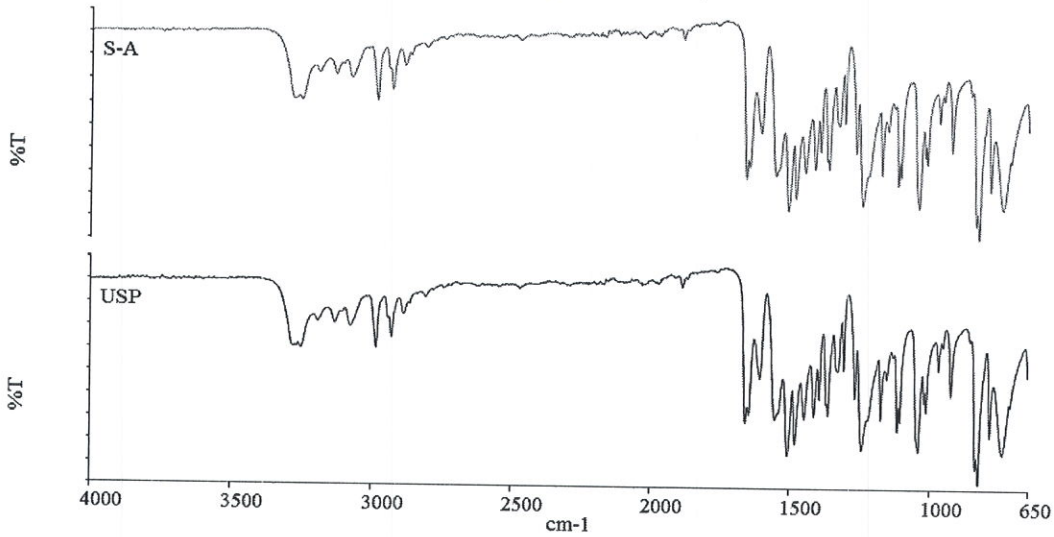
The melting range is not more than 2.0 °C and falls between 133.9 °C and 137.9 °C.

MELTING RANGE	**Result**	**U_{crm}**
S-A LOT: LRAA8978	**134.6 – 136.0°C**	**± 0.46°C, k = 2.1**
USP LOT: R066A0	**134.8 – 136.0°C**	**± 0.29°C, k = 2.1**
MELTING POINT		
S-A LOT: LRAA8978	**136.0°C**	**± 0.17°C, k = 2.2**
USP LOT: R066A0	**136.1°C**	**± 0.31°C, k = 2.2**

Note: The U_{crm} values for the USP Reference Standard do not contain a component of homogeneity, since this information is not available from the USP.

IDENTIFICATION TESTS

INFRARED SPECTROPHOTOMETRY (Comparative identification analysis demonstrates direct traceability to Pharmacopeial standards)

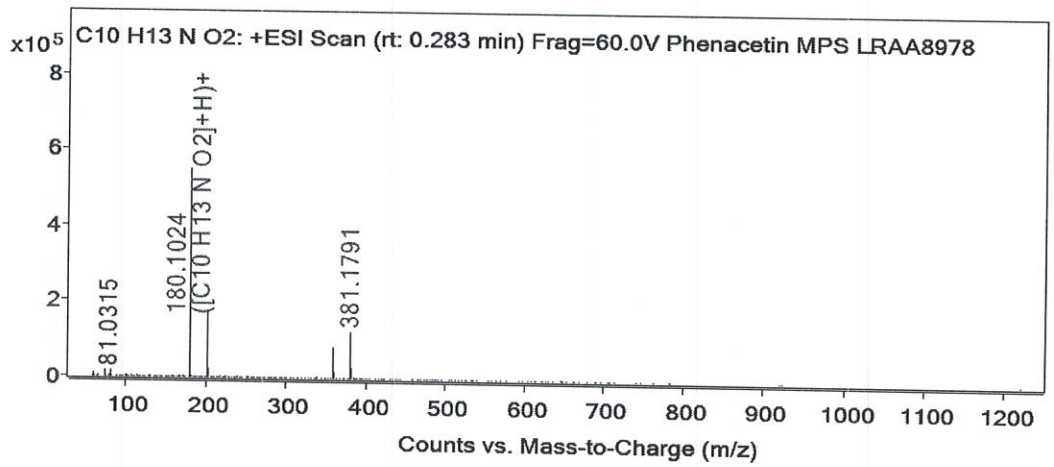


— Phenacetin Melting Point Standard S-A Lot LRAA8978
— Phenacetin Melting Point Standard USP Lot R066A0

PERKIN ELMER SPECTRUM 100
SAMPLING: UNIVERSAL ATR

MASS SPECTRUM

Method: HR-QTOF; 4.0 kV ESI+; temperature: 325 °C

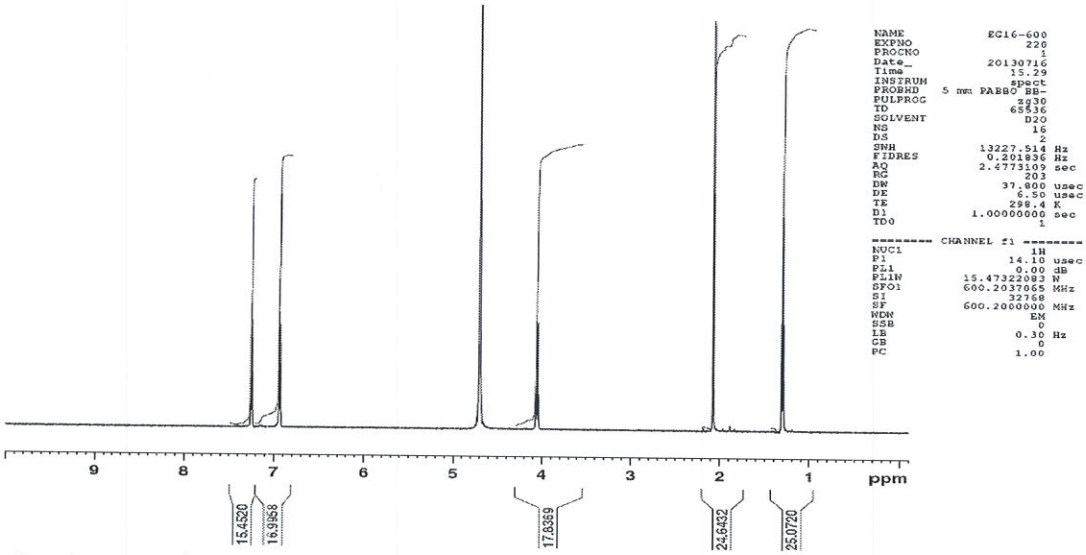


Theoretical value: 180.1025 m/z

The signal of the MS spectrum is consistent with the theoretical value and its interpretation is consistent with the structural formula.

^{1}H NMR (Data provided by an external laboratory; not in scope of accreditation)

LRAA8978 Phenacetin



Consistent with structure

ELEMENTAL ANALYSIS (Data provided by an external laboratory; not in scope of accreditation)

Exeter Analytical 440 Elemental Analyzer
Combustion method
Results of duplicate analysis:

%	Theoretical	Experimental		Mean
C	67.02	67.00	67.11	67.06
H	7.31	7.21	7.30	7.26
N	7.82	7.95	7.76	7.86

HOMOGENEITY ASSESSMENT

Homogeneity was assessed in accordance with ISO Guide 35. Completed units were sampled using a random stratified sampling protocol. The results of chemical analysis were then compared by Single Factor Analysis of Variance (ANOVA). The uncertainty due to homogeneity was derived from the ANOVA. Heterogeneity was not detected under the conditions of the ANOVA.

Analytical Method: Melting point Sample size: ~3.3mg

UNCERTAINTY STATEMENT

Uncertainty values in this document are expressed as Expanded Uncertainty (U_{crm}) corresponding to the 95% confidence interval. U_{crm} is derived from the combined standard uncertainty multiplied by the coverage factor k, which is obtained from a *t*-distribution and degrees of freedom. The components of combined standard uncertainty include the uncertainties due to characterization, homogeneity, long term stability, and short term stability (transport). The components due to stability are generally considered to be negligible unless otherwise indicated by stability studies.

STABILITY ASSESSMENT

Significance of the stability assessment will be demonstrated if the analytical result of the study and the range of values represented by the Expanded Uncertainty do not overlap the result of the original assay and the range of its values represented by the Expanded Uncertainty. The method employed will usually be the same method used to characterize the assay value in the initial evaluation.

Long Term Stability Evaluation - An assessment, or re-test, versus a Compendial Reference Standard may be scheduled, within the 3 year anniversary date of a release of a Secondary Standard. The re-test interval will be determined on a case-by-case basis.

Short Term Stability Study - It is useful to assess stability under reasonably anticipated, short term transport conditions by simulating exposure of the product to humidity and temperature stress. This type of study is conducted under controlled conditions of elevated temperature and humidity.

QC Manager

Head Quality Assurance

APPENDIX

Original Release Date:	30 September 2015
Requalification Test Date:	30 September 2016
Stability Test Date:	31 January 2019
Requalification Test Date:	31 January 2019

Manufactured and certified by Sigma-Aldrich RTC, Inc.
2931 Soldier Springs Rd, Laramie WY, USA 82070
(Phone): 1-307-742-5452 (Fax): 1-855-831-9212
email: RTCTechGroup@sial.com

ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

ANAB ACCREDITED ISO 17034 REFERENCE MATERIAL PRODUCER

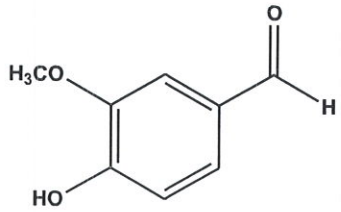
REPUBLICA MOLDOVA, mun. CHIŞINĂU S.R.L. «MIC-TAN» IDNO 1002600038292 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

Certificate of Analysis

ISO GUIDE 34
ANAB Cert# AR-1470

ISO/IEC 17025
ANAB Cert# AT-1467

VANILLIN
MELTING POINT STANDARD
CERTIFIED REFERENCE MATERIAL



NOMINAL PACKAGE SIZE: 1g

CATALOG #: PHR1091 **LOT #:** LRAB1953

CERTIFICATE VERSION: LRAB1953.2 **ISSUE DATE:** 31 July 2018

Note: Certificates may be updated due to Pharmacopeial Lot changes or the availability of new data. Check our website at: www.sigma-aldrich.com *for the most current version.*

CRM EXPIRATION: 31 December 2021 (Proper Storage and Handling Required).

RECEIPT DATE: _____
Note: this space is provided for convenience only and its use is not required.

STORAGE: Store at Room Temperature/Protect from Light, keep container tightly closed. Attachment of a 20 mm aluminum crimp seal recommended for unused portions.

CHEMICAL FORMULA: $C_8H_8O_3$ **MW:** 152.15

PHYSICAL DESCRIPTION: White powder in amber vial **CAS #:** 121-33-5

HAZARDS: Read Safety Data Sheet before using. All chemical reference materials should be considered potentially hazardous and should be used only by qualified laboratory personnel.

INSTRUCTIONS FOR USE: The internal pressure of the container may be slightly different from the atmospheric pressure at the user's location. Open slowly and carefully to avoid dispersion of the material. This material is intended for R&D use only. Not for drug, household or other uses.

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CERTIFIED MELTING RANGE/POINT (dried basis)

Specification: The observed range falls within the acceptance range: 2.1° range between 80.3 and 84.2°C (USP)

METHOD: Dry samples over silica gel for 16 hours prior to use. The melting range/melting point of the Vanillin Melting Point Standard was determined concomitantly with the melting range/melting point of the USP Vanillin Melting Point Standard using the capillary method. This method demonstrates direct traceability to the USP Reference Standard.

Reference: USP <741>
Mettler Toledo FP900 Thermosystem with FP81 Measuring Cell

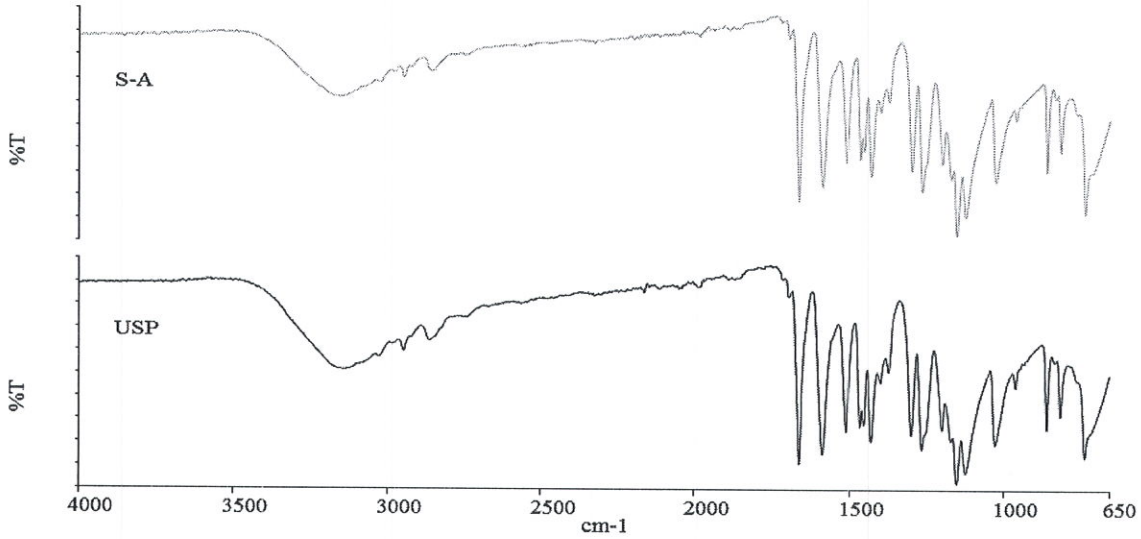
Temperature Program: 77.0 to 87.0°C at 1.0°C/min

MELTING RANGE	**Result**	**U_{crm}**
S-A LOT: LRAB1953	**81.4 –82.8 °C**	**±0.37 °C, k = 2.11**
USP LOT: L1M294	**81.4 –82.7 °C**	**±0.25 °C, k = 2.15**
MELTING POINT		
S-A LOT: LRAB1953	**82.8 °C**	**±0.32 °C, k = 2.20**
USP LOT: L1M294	**82.6 °C**	**±0.32 °C, k = 2.20**

Note: The U_{crm} values for the USP Reference Standard do not contain a component of homogeneity, since this information is not available from the USP.

IDENTIFICATION TESTS

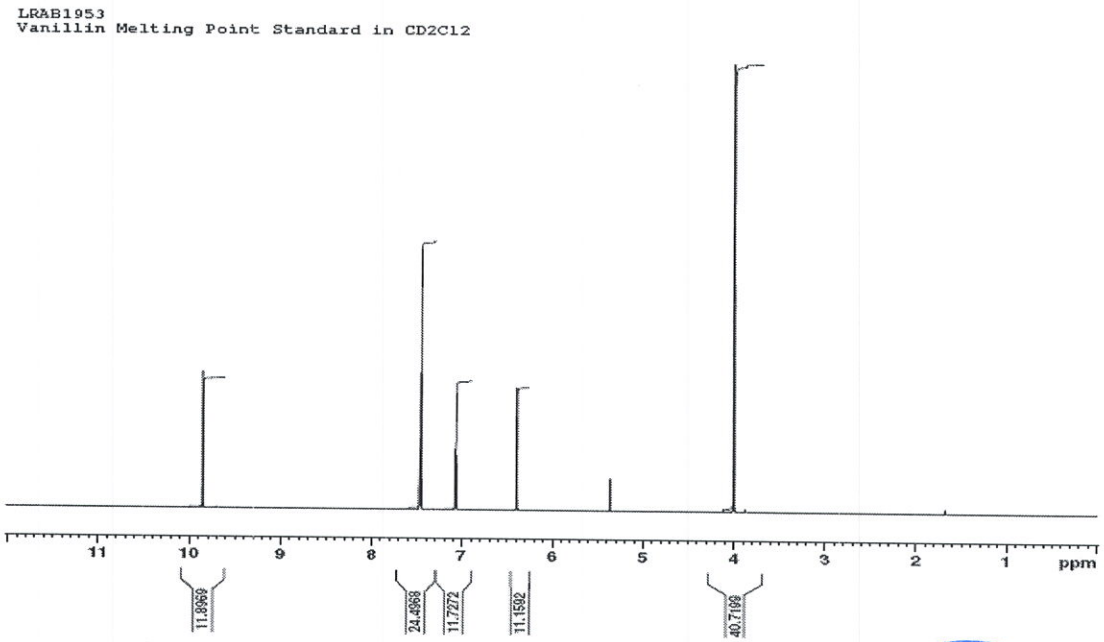
INFRARED SPECTROPHOTOMETRY (Comparative identification analysis demonstrates direct traceability to Pharmacopeial standards)



Vanillin Melting Point Standard S-A Lot LRAB1953
Vanillin Melting Point Standard USP Lot L1M294

PERKIN ELMER SPECTRUM 100
SAMPLING: UNIVERSAL ATR

^{1}H NMR (Data provided by an external laboratory; not in scope of accreditation)



Consistent with Structure

REPUBLICA MOLDOVA, mun. CHIȘINĂU
S.R.L.
«MIC-TAN»
IDNO 1002600038262
SOCIETATEA CU RĂSPUNDERE LIMITATĂ

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HOMOGENEITY ASSESSMENT

Homogeneity was assessed in accordance with ISO Guide 35. Completed units were sampled using a random stratified sampling protocol. The results of chemical analysis were then compared by Single Factor Analysis of Variance (ANOVA). The uncertainty due to homogeneity was derived from the ANOVA. Heterogeneity was not detected under the conditions of the ANOVA.

Analytical Method: Melting Point Sample size: ~3 mg

UNCERTAINTY STATEMENT

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QC Manager

Head Quality Assurance

APPENDIX

Original Release Date:	05 August 2016
Stability Test Date:	31 July 2018
Requalification Test Date:	31 July 2018

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ANAB ACCREDITED ISO GUIDE 34 REFERENCE MATERIAL PRODUCER

SIGMA-ALDRICH®

3050 Spruce Street, Saint Louis, MO 63103 USA
Email USA: techserv@sial.com Outside USA: eurtechserv@sial.com

Certificate of Analysis

Product Name:	ZINC CHLORIDE puriss. p.a., ACS reagent, reag. ISO, reag. Ph. Eur., >= 98 %
Product Number:	31650
Batch Number:	STBH2035
Brand:	Sigma-Aldrich
CAS Number:	7646-85-7
Formula:	$ZnCl_2$
Formula Weight:	136.30
Quality Release Date:	13 SEP 2017
Recommended Retest Date:	JUL 2019

TEST	SPECIFICATION	RESULT
TITRATION (KT) EDTA 0.1M	97.5 - 100.5 %	98.5 %
INSOLUBLE MATTER	≤ 0.005 %	≤ 0.005 %
PH-TEST	4.6 - 5.5	4.6
PH (METHOD)	10 %, 20 C	
HEAVY METALS	AL, CA, FE, MG AND HEAVY METALS: COMPLYING	COMPLYING
MISCELLANEOUS TESTS	OXIDE CHLORIDE (AS ZNO) ≤ 1.2 %	0.1 %
ACS SPECIFICATIONS	MEETS CURRENT ACS REQUIREMENTS	CONFORMS
CALCIUM	≤ 0.001 %	≤ 0.001 %
CADMIUM	≤ 0.001 %	≤ 0.001 %
COPPER	≤ 0.001 %	≤ 0.001 %
IRON	≤ 0.0005 %	≤ 0.0005 %
POTASSIUM	≤ 0.001 %	≤ 0.001 %
MAGNESIUM	≤ 0.001 %	≤ 0.001 %
SODIUM	≤ 0.001 %	≤ 0.001 %
LEAD	≤ 0.001 %	≤ 0.001 %
AMMONIUM (NH4+)	≤ 0.005 %	≤ 0.005 %
TOTAL NITROGEN	≤ 0.002 %	≤ 0.002 %

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SULFATE (SO4)	≤ 20 MG/KG	≤ 20 MG/KG

Claudia Mayer
Manager Quality Control
Steinheim, Germany

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Certificate of Analysis

Product Name:	ALUMINUM POTASSIUM SULFATE DODECAHYDRATE puriss. p.a., ACS reagent, reag. Ph. Eur., >= 99.5 %
Product Number:	31242
Batch Number:	BCBZ6813
Brand:	Sigma-Aldrich
CAS Number:	7784-24-9
Formula:	$AlK(SO_4)_2 * 12H_2O$
Formula Weight:	474.39
Quality Release Date:	28 NOV 2018
Recommended Retest Date:	OCT 2023

TEST	SPECIFICATION	RESULT
APPEARANCE (COLOR)	COLORLESS OR WHITE	WHITE
APPEARANCE (FORM)	POWDER OR CRYSTALS	CRYSTALS
TITRATION (ION EXCHANGE)	≥ 99.5 %	100.1 %
SOLUBILITY (COLOR)	COMPLYING	COMPLYING
SOLUBILITY (TURBIDITY)	COMPLYING	COMPLYING
SOLUBILITY (METHOD)	ACC. TO PH.EUR.	ACC. TO PH.EUR.
PH-TEST	3.0 - 3.5	3.1
PH (METHOD)	10 % IN WATER , 20C	10 % IN WATER , 20C
ACS SPECIFICATIONS	CORRESPONDS TO REQUIREMENTS	CORRESPONDS TO ACS (11TH ED.)
REMARKS ON ACS	INSOLUBLE MATTER ≤ 0.005 % HEAVY METALS (AS PB) ≤ 0.001 %	INSOLUBLE MATTER < 0.005 % HEAVY METALS (AS PB) < 0.001 %
CADMIUM (ICP)	≤ 5 MG/KG	< 5 MG/KG
COPPER (ICP)	≤ 5 MG/KG	< 5 MG/KG
IRON (ICP)	≤ 5 MG/KG	< 5 MG/KG
SODIUM (ICP)	≤ 100 MG/KG	< 100 MG/KG
LEAD (ICP)	≤ 10 MG/KG	< 10 MG/KG
ARSENIC TRACES (MHS-AAS)	≤ 2 MG/KG	< 2 MG/KG
CHLORIDE (CL)	≤ 5 MG/KG	< 5 MG/KG
ION CHROMATOGRAPHY (NH4+)	≤ 50 MG/KG	< 50 MG/KG

Dr. Reinhold Schwenninger
Quality Assurance
Buchs, Switzerland

SIGMA-ALDRICH®

3050 Spruce Street, Saint Louis, MO 63103 USA
Email USA: techserv@sial.com Outside USA: eurtechserv@sial.com

Certificate of Analysis

Product Name:	VANILLIN *ReagentPlus*, 99 %
Product Number:	V1104
Batch Number:	BCBZ6777
Brand:	Sigma-Aldrich
CAS Number:	121-33-5
Formula:	4-(HO)C_6H_3-3-(OCH_3)CHO
Formula Weight:	152.15
Quality Release Date:	15 NOV 2018

TEST	SPECIFICATION	RESULT
APPEARANCE (COLOR)	WHITE TO FAINT YELLOW	OFF WHITE
APPEARANCE (FORM)	POWDER OR CRYSTALS	POWDER
PURITY (GC AREA %)	≥ 98.5 %	99.9 %
SOLUBILITY (COLOR)	COLORLESS TO VERY FAINT YELLOW	COLORLESS
SOLUBILITY (TURBIDITY)	CLEAR	CLEAR
SOLUBILITY (METHOD)	C=50MG/ML(5%); ETHANOL	50MG/ML(5%); ETHANOL
CARBON CONTENT	62.2 - 64.1	63.1 %
INFRARED SPECTRUM	CONFORMS TO STRUCTURE	CONFORMS
WAVELENGTH (1) (UV)	344.0 - 350.0 NM	347.9 NM
MOLAR ABSORBANCY INDEX (1)	≥ 24000	25963.5
WAVELENGTH (2) (UV)	245.0 - 251.0 NM	248.2 NM
MOLAR ABSORBANCY INDEX (2)	≥ 8000	9269.0
SOLVENT (UV)	C=0.005G/L; 0.01N NAOH (PH 12.3)	C=0.005G/L; 0.01N NAOH (PH 12.3)

Dr. Reinhold Schwenninger
Quality Assurance
Buchs, Switzerland

SIGMA-ALDRICH®

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Email USA: techserv@sial.com Outside USA: eurtechserv@sial.com

Certificate of Analysis

Product Name:	*N,N*-DIMETHYLFORMAMIDE puriss. p.a., ACS reagent, reag. Ph. Eur., >= 99.8 % GC
Product Number:	33120
Batch Number:	STBH7493
Brand:	Sigma-Aldrich
CAS Number:	68-12-2
Formula:	$HCON(CH_3)_2$
Formula Weight:	73.09
Quality Release Date:	06 SEP 2018
Recommended Retest Date:	JUL 2021

TEST	SPECIFICATION	RESULT
COLOR (IN APHA)	≤ 15 APHA	< 10 APHA
TITRATABLE ACID	≤ 0.0005 MEQ/G	< 0.0005 MEQ/G
TITRATABLE BASE	≤ 0.003 MEQ/G	< 0.003 MEQ/G
PURITY (GC AREA %)	≥ 99.8 %	> 99.9 %
DENSITY D20/4	0.948 - 0.950	0.949
REFRACTIVE INDEX N20/D	1.429 - 1.431	1.4303
WATER (COULOMETR.)	≤ 0.1 %	< 0.1 %
RESIDUE (EVAPORATION)	≤ 50 PPM	25 PPM
ACIDITY	FREE ACID (AS CH3COOH): ≤ 0.003 %	< 0.001 %
ALKALINITY	FREE ALKALI (AS NH3): ≤ 0.005 %	< 0.001 %
ALUMINIUM	≤ 0.00005 %	< 0.00005 %
BARIUM	≤ 0.00001 %	< 0.00001 %
BISMUTH	≤ 0.00001 %	< 0.00001 %
BORON	≤ 0.000002 %	< 0.000002 %
CALCIUM	≤ 0.00005 %	< 0.00005 %
CADMIUM	≤ 0.000005 %	< 0.000005 %
COBALT	≤ 0.000002 %	< 0.000002 %
CHROMIUM	≤ 0.000002 %	< 0.000002 %
COPPER	≤ 0.000002 %	< 0.000002 %
IRON	≤ 0.00001 %	< 0.00001 %
POTASSIUM	≤ 0.00005 %	< 0.00005 %
LITHIUM	≤ 0.00001 %	< 0.00001 %
MAGNESIUM	≤ 0.00001 %	< 0.00001 %
MANGANESE	≤ 0.000002 %	< 0.000002 %

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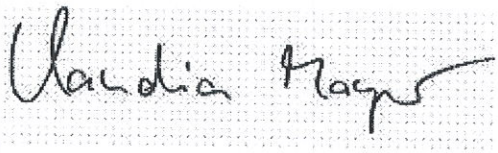
MOLYBDENUM	≤ 0.00001 %	< 0.00001 %
SODIUM	≤ 0.0001 %	< 0.0001 %
NICKEL	≤ 0.000002 %	< 0.000002 %
LEAD	≤ 0.00001 %	< 0.00001 %
TIN	≤ 0.00001 %	< 0.00001 %
STRONTIUM	≤ 0.00001 %	< 0.00001 %
ZINC	≤ 0.00001 %	< 0.00001 %



Claudia Mayer
Manager Quality Control
Steinheim, Germany