

Complete Final Version of the Certificate of Analysis

(02-0898)

Dr. Kimberly Spence

**Title: Precursor Preference in Surfactant Synthesis of
Newborns**



Cambridge Isotope Laboratories, Inc.

50 Frontage Road, Andover, MA 01810-5413 USA
PH: 800.322.1174 (USA) PH: 978.749.8000
FAX: 978.749.2768 URL: <http://www.isotope.com>

Certificate of Analysis

Product: Sodium Acetate ($1-^{13}\text{C}$, 99%)

Grade: Metabolic

Catalog #: CLM-156-MG

Formula: $\text{CH}_3^*\text{COONa}$

Molecular Weight: 83.03

CAS #: [23424-28-4]

Batch #: PR-12777

Production Completed: 09/06/01

Method of Analysis

Test	Reference/Method	Specification	Results
Appearance	USP 23	White, crystalline solid	Pass
Identification	^1H -NMR	Conforming	Pass
	^{13}C -NMR	Conforming	Pass
Chemical Purity	Titration	98-101%	99.2%
Isotopic Purity	GC/MS	≥ 99 atom%	98.7%
Bioburden	USP/Sterility	Sterile	Pass
Endotoxin	USP/Pyrogen-Rabbit	USP 23 <151>	Pass
	USP/Pyrogen-LAL	≤ 0.03 EU/mg	< 0.002 EU/mg
Heavy Metals	USP/ASTM	≤ 10 ppm	< 10 ppm
pH	CIL	7.5 - 9.2	9.2
Water Content	Karl-Fischer	$\leq 1\%$	0.66%
Clarity of Solution (50 mg/ ml)	CIL	Clear	Pass

Product should be stored in a cool, dry place away from light.

Certified:


Eloise C. Young Ph.D., Technical Service Chemist


Date

DATE 02/10/2004

Hexadecanoic Acid-1,2,3,4-¹³C₄, Potassium Salt (Potassium palmitate)

ISOTEC NUMBER T83-42081

ALDRICH NUMBER 605808

BATCH NUMBER CR1261

METHODS	SPECIFICATIONS	TEST RESULTS
% Water	< = 1%	0.95%
¹ H-NMR (FT)	Structure and purity verification	Meets requirement
¹ H-NMR (FT)	Minimum 99 atom% ¹³ C	99.0 atom% ¹³ C
¹³ C-NMR	Structure and purity verification	Meets requirement
m.p.	Conforms to standard	262-263 °C
Appearance	White powder	White powder



JOHN KUO, Ph. D.
Analytical & Quality Control
Supervisor



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CERTIFICATE OF ANALYSIS

Product Name: SODIUM ACETATE
(Isotopic Label & Enrichment Specification) (1-¹³C, 99%) STERILITY/PYROGENICITY TESTED

Lot Number: PR-15759

Catalog Number: CLM-156-SP

Product Information

Chemical Purity Specification: >98%

Labeled CAS Number: 23424-28-4

Unlabeled CAS Number: 127-09-3

Molecular Weight: 83.0

Chemical Formula: CH₃*COONa

Storage: Store at room temperature away from light and moisture.

Stability: Stable if stored under recommended conditions.

Certification

Cambridge Isotope Laboratories, Inc. guarantees that this material meets or exceeds the specifications stated. Absolute identity as well as chemical and isotopic purities are assured by the use of unambiguous synthetic routes and multiple chemical analyses whenever possible.

Approved by: Deborah E. Costa

Deborah E. Costa, Quality Assurance

Quality Control Tests and Results

GC/MS for Isotopic Enrichment	99.1%
Karl Fischer Titration for Total Water Content	482 ppm
Heavy Metals Analysis	<10 ppm
Microbial Limits	Pass
pH Analysis	8.7
Endotoxin Test (LAL) of Bulk Lot	<0.03 EU/mg
Titration for Chemical Purity	99.5%
¹ H NMR for Chemical Purity	Pass
¹³ C NMR for Identification	Conforms



Clinical Laboratories
 One Children's Place
 St. Louis, MO 63110

Chart Printed: 02/13/04 4:31 AM Patient Name:
 Admit Date: 07/22/2002 Med Record Number
 Discharge Date: Birthdate/Age/Sex: / Unknown / Unknown
 Doctor: Hamvas, Aaron Patient Location:
 Client: Pediatrics Newborn
 Med NEM Study (SLCH client)

MICROBIOLOGY - ROUTINE

PROCEDURE: Aerobic Culture (Routine)
 SOURCE: Drainage COLLECTED: 02/12/04 1343
 BODY SITE: Infusaport STARTED: 02/12/04 1400
 FREE TEXT SOURCE: ACCESSION: 04-043-003427

*** DIRECT SPECIMEN EXAMINATION ***

Stain
 Cytospin gram stain shows:
 No polymorphonuclear leukocytes seen.
 No organisms seen.

REPORTED: 02/12/04 1614

Nur Palm Lot CR1261-Sp.

PROCEDURE: Aerobic Culture (Routine)
 SOURCE: Environmental COLLECTED: 07/22/02 1030
 BODY SITE: None STARTED: 07/22/02 1412
 FREE TEXT SOURCE: ACCESSION: 02-203-003676

*** FINAL REPORT***
 No growth

REPORTED: 07/24/02 0922

MICROBIOLOGY - MYCOLOGY

PROCEDURE: Mycology Culture
 SOURCE: Environmental COLLECTED: 07/22/02 1030
 BODY SITE: STARTED: 07/22/02 1413
 FREE TEXT SOURCE: ACCESSION: 02-203-003721

*** FINAL REPORT***
 Negative

REPORTED: 08/18/02 1232

*** Interpretive Results ***
 Cultures are held for 4 weeks. They are examined daily for the first week, and weekly thereafter.

* Abnormal A Alert f Footnote ^ Corrected L Low H High i Interp Data

Cumulative

Bio-Science Research Institute, Inc.

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Phone (909) 628-3007
Fax (909) 590-8948

Director: Tae W. Kang, Ph.D
FDA Registration No.: 2022038
DEA Registration No.: RB0177887
www.bio-science-research.com

TEST: Assay for Sodium Acetate and Potassium Palamitate
CLIENT: Washington Univ School of Med, Div of Newborn Med
SAMPLE: Isotope preparation
Sample Description: clear colorless liquid
date received: 2-13-04 date reported: 2-23-04
our work No.: Wash021304 your PO No.: 21310J
Method: Flame Photometric Raw Data Page: Wash

Results

Analytes

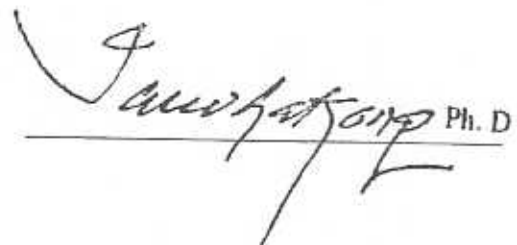
Sodium Acetate
Potassium Palamitate

Results

10.66 mg/ml
7.2 mEq/l

New Palm Lot CR1261
Acet Lot. PR 13851

Authorized Signature

 Ph. D

Bio-Science Research Institute, Inc.

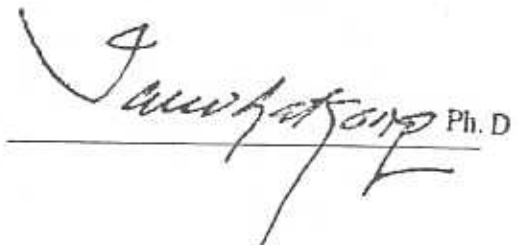
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TEST: LAL (Bacterial Endotoxin) Test
CLIENT: Washington Univ School of Med, Div of Newborn Med
SAMPLE: Isotope preparation
Sample Description: clear colorless liquid
date received: 2-13-04 date reported: 2-23-04
our work No.: Wash02304 your PO No.: 21310J
Method: Gel Clot Raw Data Page: Wash
Results

Less than 1 EU/ml

Authorized Signature

 Tae W. Kang Ph. D

Bio-Science Research Institute, Inc.

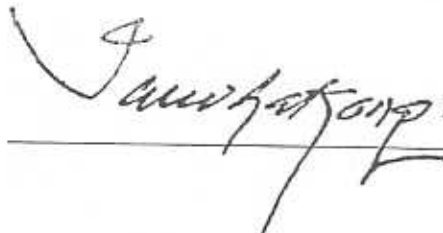
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TEST: Particulate Matter
CLIENT: Washington Univ School of Med, Div of Newborn Med
SAMPLE: Isotope preparation
Sample Description: clear colorless liquid
date received: 2-13-04 date reported: 2-23-04
our work No.: Wash021304 your PO No.: 21310J
Method: Microscopic Raw Data Page: Wash
Results

Conforms

Authorized Signature

 Ph.D