

Scientific Documentation

Edetate Disodium, USP, EP, JP, bioCERTIFIED (TM)

Not appropriate for regulatory submission.

Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp
769 Jersey Avenue
New Brunswick, NJ 08901
Phone 732.214.1300



Table of Contents

- Product Specification
- Certificate of Analysis Sample(s)
- Safety Data Sheet (SDS)
- Certification of Current Good Manufacturing Practices (cGMP)
- Manufacturing Process Flowchart
- Technical Statements
- Elemental Impurities Statement
- Residual Solvents Statement
- General Label Information – Sample Label

Specification for Edetate Disodium, USP, EP, JP, bioCERTIFIED (TM) (E9600)

Item Number	E9600
Item	Edetate Disodium, USP, EP, JP, bioCERTIFIED (TM)
CAS Number	6381-92-6
Molecular Formula	$C_{10}H_{14}N_2Na_2O_8 \cdot 2H_2O$
Molecular Weight	372.24
MDL Number	
Synonyms	Ethylenediaminetetraacetic Acid Disodium Salt ; EDTA, Disodium ; (Ethylenedinitrilo)tetraacetic Acid Disodium

Test	Specification	
	Min	Max
APPEARANCE		
ASSAY (DRIED BASIS, USP)	99.0	101.0 %
ASSAY (AS DIHYDRATE, EP)	98.5	101.0 %
ASSAY (AS DIHYDRATE, JP)	99.0 %	
APPEARANCE OF SOLUTION (EP)	CLEAR AND COLORLESS	
CLARITY AND COLOR OF SOLUTION (JP)	CLEAR AND COLORLESS	
pH OF A 5% SOLUTION @ 25°C (USP)	4.0	6.0
pH OF A 5% SOLUTION @ 20°C (EP)	4.0	5.5
pH OF A 1% SOLUTION @ 25°C (JP)	4.3	4.7
LOSS ON DRYING (USP)	8.7	11.4 %
RESIDUE ON IGNITION (JP)	37.0	39.0 %
CALCIUM (USP)	NO PRECIPITATE FORMS	
CYANIDE (JP)	NO MORE COLOR THAN CONTROL	
IRON (EP)		80 ppm
HEAVY METALS (JP)		10 ppm
ARSENIC (JP)		2 ppm
ELEMENTAL IMPURITIES	AS REPORTED	
NITRILOTRIACETIC ACID (USP)		0.1 %

Test	Specification	
	Min	Max
IMPURITY A (EP)		0.1 %
MICROBIAL LIMITS:		
BACTERIAL ENDOTOXIN (BET)		2.5 EU/mg
TAMC		1000 CFU/g
TYMC		100 CFU/g
IDENTIFICATION (A) FTIR	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	RED COLOR IS DISCHARGED	
IDENTIFICATION (C)	POSITIVE FOR SODIUM	
IDENTIFICATION (B) EP	NO PRECIPITATE IS FORMED	
IDENTIFICATION (C) EP	NO PRECIPITATE IS FORMED	
IDENTIFICATION (1) JP	PURPLE COLOR DEVELOPS	
IDENTIFICATION (2) JP	240	244°C
EXPIRATION DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS	AS REPORTED	
MONOGRAPH EDITION		
MONOGRAPH EDITION.		
MONOGRAPH EDITION..		

Spectrum Chemical Mfg Corp

Corporate Headquarters: ***West Coast Facility:***
769 Jersey Ave. 14422 S. San Pedro St.
New Brunswick, NJ 08901 Gardena, CA 90248
732.214.1300 310.516.8000

Certificate Of Analysis

Item Number	E9600	Lot Number	4LH0004
Item	Edetate Disodium, USP, EP, JP, bioCERTIFIED (TM)	CAS Number	6381-92-6
Molecular Formula	C ₁₀ H ₁₄ N ₂ Na ₂ O ₈ •2H ₂ O	Molecular Weight	372.24

TEST	SPECIFICATION		RESULT
	MIN	MAX	
APPEARANCE			WHITE POWDER
ASSAY (DRIED BASIS, USP)	99.0	101.0 %	100.0 %
ASSAY (AS DIHYDRATE, EP)	98.5	101.0 %	99.0 %
ASSAY (AS DIHYDRATE, JP)	99.0 %		99.1 %
APPEARANCE OF SOLUTION (EP)	CLEAR AND COLORLESS		CLEAR AND COLORLESS
CLARITY AND COLOR OF SOLUTION (JP)	CLEAR AND COLORLESS		CLEAR AND COLORLESS
pH OF A 5% SOLUTION @ 25°C (USP)	4.0	6.0	4.53
pH OF A 5% SOLUTION @ 20°C (EP)	4.0	5.5	4.53
pH OF A 1% SOLUTION @ 25°C (JP)	4.3	4.7	4.596
LOSS ON DRYING (USP)	8.7	11.4 %	9.3 %
RESIDUE ON IGNITION (JP)	37.0	39.0 %	38.18 %
CALCIUM (USP)	NO PRECIPITATE FORMS		NO PRECIPITATE FORMS
CYANIDE (JP)	NO MORE COLOR THAN CONTROL		NO MORE COLOR THAN CONTROL
IRON (EP)		80 ppm	<80 ppm
HEAVY METALS (JP)		10 ppm	<10 ppm
ARSENIC (JP)		2 ppm	<0.05 ppm
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
NITRILOTRIACETIC ACID (USP)		0.1 %	0.0 %
IMPURITY A (EP)		0.1 %	0.0 %
MICROBIAL LIMITS:			.

TEST	SPECIFICATION		RESULT
	MIN	MAX	
BACTERIAL ENDOTOXIN (BET)		2.5 EU/mg	<2.5 EU/mg
TAMC		1000 CFU/g	<1000 CFU/g
TYMC		100 CFU/g	<100 CFU/g
IDENTIFICATION (A) FTIR	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	RED COLOR IS DISCHARGED		RED COLOR IS DISCHARGED
IDENTIFICATION (C)	POSITIVE FOR SODIUM		POSITIVE FOR SODIUM
IDENTIFICATION (B) EP	NO PRECIPITATE IS FORMED		NO PRECIPITATE FORMED
IDENTIFICATION (C) EP	NO PRECIPITATE IS FORMED		NO PRECIPITATE FORMED
IDENTIFICATION (1) JP	PURPLE COLOR DEVELOPS		PURPLE COLOR DEVELOPS
IDENTIFICATION (2) JP	240	244°C	240.9°C
EXPIRATION DATE			16-APR-2025
DATE OF MANUFACTURE			17-APR-2022
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS USED
MONOGRAPH EDITION			USP 2022
MONOGRAPH EDITION.			EP 10
MONOGRAPH EDITION..			JP 18

Certificate of Analysis Results Entered By:

SVANGOOR
Swetha Vangoor
27-SEP-22 12:23:09

Spectrum Chemical Mfg Corp
777 Jersey Avenue
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

BPATEL
Bhargavi Patel
28-SEP-22 05:43:24

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

SAFETY DATA SHEET

spectrum®



Revision date 17-December-2021

Revision Number 2

1. Identification

Product identifier

Product Name EDETATE DISODIUM, DIHYDRATE, USP, EP. IP

Other means of identification

Product Code(s) E9600

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use No information available

Restrictions on use No information available

Details of the supplier of the safety data sheet

Supplier Address

Spectrum Chemical Mfg. Corp.
14422 South San Pedro St.
Gardena, CA 90248
(310) 516-8000

Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

2. Hazard(s) identification

Classification

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Hazard statements

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

The product contains no substances which at their given concentration, are considered to be hazardous to health.

Appearance Crystalline powder

Physical state Solid

Odor No information available

Other information

No information available.

3. Composition/information on ingredients**Substance**

Chemical name	CAS No	Weight-%	Trade secret
Edetate Disodium, Dihydrate	6381-92-6	100	*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. First-aid measures**Description of first aid measures**

Inhalation	Remove to fresh air.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash skin with soap and water.
Ingestion	Clean mouth with water and drink afterwards plenty of water.

Most important symptoms and effects, both acute and delayed**Symptoms** No information available.**Indication of any immediate medical attention and special treatment needed****Note to physicians** Treat symptomatically.**5. Fire-fighting measures**

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
Specific hazards arising from the chemical	No information available.
Hazardous combustion products	Carbon Monoxide, Carbon Dioxide. Nitrogen oxides (NOx). Sodium oxides.
Explosion data	
Sensitivity to mechanical impact	none.
Sensitivity to static discharge	none.
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Pick up and transfer to properly labeled containers.

7. Handling and storage

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep container tightly closed in a dry and well-ventilated place.

8. Exposure controls/personal protection

Control parameters

Exposure Limits The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection No special protective equipment required.

Skin and body protection No special protective equipment required.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid

Appearance Crystalline powder

Color	White
Odor	No information available
Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	no data available	None known
Melting point / freezing point	252 °C / 485.6 °F	None known
Boiling point / boiling range	no data available	None known
Flash point	no data available	None known
Evaporation rate	no data available	None known
Flammability (solid, gas)	no data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	1.77	None known
Water solubility	Soluble in water	None known
Solubility(ies)	no data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	no data available	None known
Decomposition temperature		None known
Kinematic viscosity	no data available	None known
Dynamic viscosity	No data available	None known
<u>Other information</u>		
Explosive properties	No information available	
Oxidizing properties	No information available	
Softening point	No information available	
Molecular weight	372.24	
VOC Content (%)	No information available	
Liquid Density	No information available	
Bulk density	No information available	

10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.
Hazardous decomposition products	None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Acute toxicity

Numerical measures of toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Edetate Disodium, Dihydrate 6381-92-6	> 2000 mg/kg (Rat)	-	-

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation No information available.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

Other adverse effects No information available.

Interactive effects No information available.

12. Ecological information

Ecotoxicity

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Edetate Disodium, Dihydrate 6381-92-6	67 mg/l EC50 Chlorococcales (Green algae order) 24 h	-	-	> 100 mg/L 24h

Persistence and degradability No information available.

Bioaccumulation Inherently biodegradable.

Other adverse effects No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

14. Transport information

<u>DOT</u>	not regulated
<u>TDG</u>	not regulated
<u>MEX</u>	not regulated
<u>ICAO (air)</u>	not regulated
<u>IATA</u>	not regulated
<u>IMDG</u>	not regulated
<u>RID</u>	not regulated
<u>ADR</u>	not regulated
<u>ADN</u>	not regulated

15. Regulatory information

International Inventories

TSCA Not listed

Note *Contact supplier for details. One or more substances in this product are either not listed on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise exempted from inventory listing requirements

DSL/NDSL	Complies
EINECS/ELINCS	Does not Comply
ENCS	This product complies with ENCS:
IECSC	This product complies with China:
KECL	Does not Comply
PICCS	Complies
AICS	All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS).

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA

Health hazards 0

Flammability 0

Instability 0

Physical and chemical properties -

HMIS

Health hazards 0

Flammability 0

Physical hazards 0

Personal protection X

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value		

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organization for Economic Co-operation and Development Environment, Health, and Safety Publications

Organization for Economic Co-operation and Development High Production Volume Chemicals Program

Organization for Economic Co-operation and Development Screening Information Data Set

World Health Organization

Revision date

17-December-2021

Revision Note

No information available.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet



Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
E9600	Edetate Disodium, USP, EP, JP, bioCERTIFIED™

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

Oralia Chavez
Quality Assurance Specialist

E9600, Edetate Disodium, USP, EP, JP, bioCERTIFIED™

Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.

Nitrosamine Statement

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

Animal Testing Statement

The above mentioned catalog item has been tested on animals before 2014.

Organic Compliance Statement

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

Shelf Life Statement

The above mentioned catalog item is typically assigned a shelf life of 36 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

Other Chemicals Statement

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- Aflatoxins
- Antibiotics
- Bisphenol A (BPA)
- CMR Substances
- Parabens
- Pesticides
- Phthalates
- Preservatives

Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.



USE CARE: This material has been evaluated per GHS/OSHA criteria and is not classified as hazardous. All chemicals may pose unknown hazards and must be used with caution. Use personal protection and safe handling methods consistent with proper workplace safety practices. Consult SDS for additional properties and precautions. If adverse reaction occurs seek medical attention.

KEEP FROM CHILDREN

WARNING:

Cancer and Reproductive Harm-
www.P65Warnings.ca.gov

E9600 **SIZ SY**
Edetate Disodium
(EDTA, Disodium; Ethylene-
diaminetetraacetic Acid Disodium Salt)

USP, EP, JP, bioCERTIFIED™

CAS 6381-92-6



CAUTION: For manufacturing, processing or repacking. Not for use in parenteral applications. **Read and understand the label and Safety Data Sheet (SDS) prior to use.**

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

$C_{10}H_{14}N_2Na_2O_8 \cdot 2H_2O$ F.W. 372.24

Not Sterile.

Assay (Dried Basis, USP).....	99.0-101.0%
Assay (as Dihydrate, EP).....	98.5-101.0%
Assay (as Dihydrate, JP).....	Min. 99.0%
Appearance of Solution (EP).....	To pass test
Clarity and Color of Solution (JP).....	To pass test
pH of a 5% Solution @ 25°C (USP).....	4.0-6.0
pH of a 5% Solution @ 20°C (EP).....	4.0-5.5
pH of a 1% Solution @ 25°C (JP).....	4.3-4.7
Loss on Drying (USP).....	8.7-11.4%
Residue on Ignition (JP).....	37.0-39.0%

MAXIMUM LIMITS

Calcium (USP).....	To pass test
Cyanide (JP).....	To pass test
Iron (EP).....	.80 ppm
Heavy Metals (JP).....	.10 ppm
Arsenic (JP).....	.2 ppm
Elemental Impurities.....	As reported
Nitriiotriacetic Acid (USP).....	.0.1%
Impurity A (EP).....	.0.1%
Residual Solvents.....	To pass test

G 3/K12GHS

?

Lot No. XQ####

Spectrum Chemical Mfg Corp

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New Brunswick, NJ 08901
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