

### **Scientific Documentation**

# Sucrose, NF, EP, BP, bioCERTIFIED (TM), Endotoxin Tested

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
Safety Data Sheet (SDS)
Certification of Current Good Manufacturing Practices (cGMP)
Technical Statements
Elemental Impurities Statement
Residual Solvents Statement
General Label Information – Sample Label



# Specification for Sucrose, NF, EP, BP, bioCERTIFIED (TM), Endotoxin Tested (S9700)

Item Number	S9700
Item	Sucrose, NF, EP, BP, bioCERTIFIED (TM), Endotoxin Tested
CAS Number	57-50-1
Molecular Formula	$C_{12}H_{22}O_{11}$
Molecular Weight	342.30
MDL Number	
Synonyms	Beta-D-Fructofuranosyl-alpha-D-glucopyranoside; Cane Sugar

Test	Specification	
	Min	Max
APPEARANCE	WHITE, COLORLESS POWDER TO FINE CRYSTALS	
APPEARANCE OF SOLUTION	TO PASS TEST	
SPECIFIC ROTATION @ 20°C	+66.3 to +67.0°	
LOSS ON DRYING		0.1 %
SULFITE (as SO <sub>2</sub> )		10 ppm
CONDUCTIVITY		35 ?S/cm
COLOR VALUE		45
REDUCING SUGARS	TO PASS TEST	
ELEMENTAL IMPURITIES	AS REPORTED	
MICROBIAL LIMITS:		
BACTERIAL ENDOTOXINS		0.25 EU/mg
TOTAL AEROBIC MICROBIAL COUNT		100 cfu/g
TOTAL YEAST AND MOLD COUNT		100 cfu/g
BILE TOLERANT GRAM-NEGATIVE BACTERIA	NONE DETECTED	
ESCHERICHIA COLI	NONE DETECTED	
SALMONELLA	NONE DETECTED	
CANDIDAS ALBICANS	NONE DETECTED	
STAPHYLOCOCCUS AUREUS	NONE DETECTED	

Test	Specification		
	Min	Max	
PSEUDOMONAS AERUGINOSA	NONE DETECTED		
IDENTIFICATION	TO PASS TEST		
RETEST DATE			
DATE OF MANUFACTURE			
MONOGRAPH EDITION			
MONOGRAPH EDITION.			
RESIDUAL SOLVENTS	AS REPORTED		

#### Spectrum Chemical Mfg Corp

Corporate Headquarters:West Coast Facility:769 Jersey Ave.14422 S. San Pedro St.New Brunswick, NJ 08901Gardena, CA 90248732.214.1300310.516.8000



# **Certificate Of Analysis**

Item Number	S9700	Lot Number	4LK0030
Item	Sucrose, NF, EP, BP, bioCERTIFIED (TM), Endotoxin Tested	CAS Number	57-50-1
Molecular Formula	$C_{12}H_{22}O_{11}$	Molecular Weight	342.30

TECT	SPECIFICATION		DECLU T
TEST	MIN	MAX	RESULT
APPEARANCE	White, colorless powder to fine crystals		WHITE FINE CRYSTALS
APPEARANCE OF SOLUTION	TO PASS TEST		PASSES TEST
SPECIFIC ROTATION @ 20°C	+66.3 to+67.09°		+66.86°
LOSS ON DRYING		0.1 %	0.07 %
SULFITE (as SO <sub>2</sub> )		10 ppm	<10 ppm
CONDUCTIVITY		35 μS/cm	6.728 μS/cm
COLOR VALUE		75	36.5
REDUCING SUGARS	TO PASS TEST		PASSES TEST
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
MICROBIAL LIMITS:			
BACTERIAL ENDOTOXINS		0.6 EU/g	<0.6 EU/g
TOTAL AEROBIC MICROBIAL COUNT		100 cfu/g	<100 cfu/g
TOTAL YEAST AND MOLD COUNT		100 cfu/g	<100 cfu/g
BILE TOLERANT GRAM-NEGATIVE BACTERIA	None detected		NONE DETECTED
ESCHERICHIA COLI	None detected		NONE DETECTED
SALMONELLA	None detected		NONE DETECTED
CANDIDAS ALBICANS	None detected		NONE DETECTED
STAPHYLOCOCCUS AUREUS	None detected		NONE DETECTED
PSEUDOMONAS AERUGINOSA	None detected		NONE DETECTED
RESIDUAL SOLVENTS	AS REPORTED		
IDENTIFICATION	TO PASS TEST		PASSES TEST
RETEST DATE			03-JUN-2024

TECT	SPECIFICATION		DECLUIT.
TEST	MIN	MAX	RESULT
CLASS 3 (solvent) / 2-PROPANOL			<5000 ppm
MANUFACTURE DATE			03-JUN-2022

Certificate of Analysis Results Entered By:

SVANGOOR Swetha Vangoor 19-DEC-22 06:15:19

Spectrum Chemical Mfg Corp 777 Jersey Avenue New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS Allison Williams 19-DEC-22 14:11:57

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.





Revision date 01-June-2021 Revision Number 1

#### 1. Identification

**Product identifier** 

SUCROSE, NF, EP, BP, BIOCERTIFIED(TM), ENDOTOXIN TESTED **Product Name** 

Other means of identification

S9700 Product Code(s)

**Synonyms** None

Recommended use of the chemical and restrictions on use

No information available Recommended use

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

Combustible dust Yes

#### Hazards not otherwise classified (HNOC)

Not applicable

#### Label elements

Warning

Crystals

#### Hazard statements

May form combustible dust concentrations in air

Appearance Crystalline powder or

Physical state Solid

**Odor** No information available

#### **Precautionary Statements - Prevention**

Keep away from all ignition sources including heat, sparks, and flame

Keep container closed and grounded

Prevent dust accumulations to minimize explosion hazard

#### Other information

No information available.

#### 3. Composition/information on ingredients

#### Substance

Chemical name	CAS No	Weight-%	Trade secret
Sucrose	57-50-1	100	*

<sup>\*</sup>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

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

Avoid generation of dust. Fine dust dispersed in air may ignite.

#### **Explosion data**

Sensitivity to mechanical impact none.

Sensitivity to static discharge yes.

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. Avoid generation of dust. Avoid contact with eyes. Use

personal protective equipment as required. Do not breathe dust. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Take precautionary

measures against static discharges.

**Other information** Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

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

Methods for cleaning up Take up with inert, damp, non-combustible material using clean non-sparking tools and

place into loosely covered plastic containers for later disposal. 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. Ensure adequate

ventilation. Avoid generation of dust. Do not breathe dust. Avoid contact with eyes. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use spark-proof tools and explosion-proof equipment. Take precautionary measures

against static discharges.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up.

Keep out of the reach of children.

#### 8. Exposure controls/personal protection

#### Control parameters

Exposure Limits

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Sucrose	No data available	15 mg/m³ TWA	-
57-50-1		5 mg/m³ TWA	

#### **Appropriate engineering controls**

Engineering controls Showers

Eyewash stations Ventilation systems.

#### Individual protection measures, such as personal protective equipment

**Eye/face protection** Wear safety glasses with side shields (or goggles).

**Skin and body protection**No special protective equipment required.

No protective equipment is needed under normal use conditions. If exposure limits are Respiratory protection

exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Do not breathe dust.

#### 9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid

Crystalline powder or Crystals **Appearance** 

Color White

Odor No information available Odor threshold No information available

Property Values Remarks • Method

None known no data available pН 185 - 186 °C / 365 - 366.8 °F Melting point / freezing point 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 No data available

limits

Lower flammability or explosive No data available

limits

Vapor pressure No data available None known Vapor density no data available None known Relative density 1.587 None known None known Water solubility Soluble in water Solubility(ies) Slightly soluble in Ethanol None known

Insoluble in Ether

Moderately soluble in glycerol Moderately soluble in pyridine

**Partition coefficient** -3.70None known **Autoignition temperature** no data available None known None known

**Decomposition temperature** 

Kinematic viscosity no data available None known Dynamic viscosity No data available None known

Other information

No information available **Explosive properties Oxidizing properties** No information available Softening point No information available

Molecular weight 342.30

**VOC Content (%)** No information available **Liquid Density** No information available No information available **Bulk density** 

#### 10. Stability and reactivity

No information available. Reactivity

Chemical stability Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid Excessive heat. Heating in air. dust formation.

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

**Product Information** 

Inhalation Specific test data for the substance or mixture is not available. May cause irritation of

respiratory tract.

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.

Specific test data for the substance or mixture is not available. Ingestion

Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** No information available.

**Acute toxicity** 

**Numerical measures of toxicity** 

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sucrose	29700 mg/kg (Rat)	-	-
57-50-1			

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

Skin corrosion/irritation No information available. No information available. Serious eye damage/eye irritation Respiratory or skin sensitization No information available. Germ cell mutagenicity No information available.

No information available.

No information available. STOT - single exposure STOT - repeated exposure No information available. Target organ effects respiratory system, Eyes.

No information available. **Aspiration hazard** 

Other adverse effects No information available.

Interactive effects No information available.

#### 12. Ecological information

The environmental impact of this product has not been fully investigated. **Ecotoxicity** 

Persistence and degradability

**Bioaccumulation** 

Reproductive toxicity

No information available. 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

**DOT** not regulated

TDG not regulated

MEX not regulated

ICAO (air) not regulated

IATA not regulated

IMDG not regulated

RID not regulated

ADR not regulated

ADN not regulated

#### 15. Regulatory information

#### International Inventories

TSCA Complies

DSL/NDSL Complies EINECS/ELINCS Complies

**ENCS IECSC**This product complies with ENCS:
This product complies with China:

KECL Complies 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

#### <u>NFPA</u>

Health hazards 0 Flammability 1

**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 01-June-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
S9700	Sucrose, NF, EP, BP, bioCERTIFIED ™
	Endotoxin Tested

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

Order Clony



# **S9700**, Sucrose, NF, EP, BP, bioCERTIFIED ™, Endotoxin Tested

#### **Source Statement**

The above mentioned catalog item is manufactured from plant origin material (sugarcane). No animal 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

#### **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 not been tested on animals.

#### **Shelf Life Statement**

The above mentioned catalog item is typically assigned a shelf life of 24 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

Pesticides

Antibiotics



## RE: Elemental Impurities - Sucrose, NF, EP, BP, bioCERTIFIED ™, Endotoxin Tested (Cat# S9700)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at <a href="mailto:TechServices@spectrumchemical.com">TechServices@spectrumchemical.com</a>.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132 WEST COAST FACILITY

14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843



### RE: Residual Solvents - Sucrose, NF, EP, BP, bioCERTIFIED ™, Endotoxin Tested (Cat# S9700)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
2-Propanol	3	< 5000 ppm

No Class 1, Class 2 or other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at <a href="mailto:TechServices@spectrumchemical.com">TechServices@spectrumchemical.com</a>.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

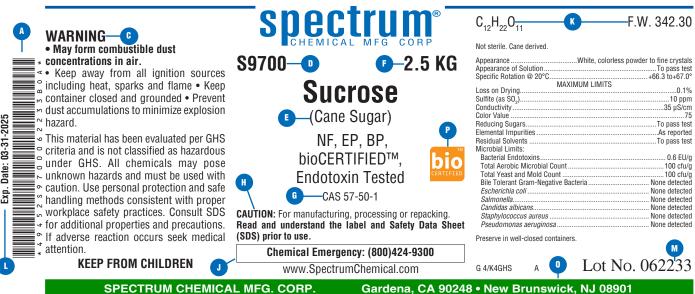
769 Jersey Avenue New Brunswick, NJ 08901 PHONE 732.214.1300 FAX 732.246.7132 WEST COAST FACILITY

14422 South San Pedro Street
Gardena, California 90248
PHONE 310.516.8000
FAX 310.516.9843



#### **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.



- A Bar Code
- GHS Hazard Pictograms
- Warning, Safety Data and Precautionary Information
- Product Catalog Number
- Item Name, Form, Grade
- Size/Quantity

- Chemical Abstracts Service (CAS) Registry Number
- Caution Information
- DOT Shipping Information
- Toll-Free 24-Hour Chemical **Emergency Telephone Number**
- Empirical Formula, Formula Weight and Technical Specifications Panel
- Expiration Information
- Lot Number
- Kosher Certified by Kosher Supervision of America (KSA).
- Storage Color Band
- Halal Certified by IFANCA
- bioCertified

This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

#### Spectrum Chemical Mfg Corp

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