

Scientific Documentation

Sodium Alginate, NF

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





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Product Specification Certificate of Analysis 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 Sodium Alginate, NF (S1118)

Item Number	S1118
Item	Sodium Alginate, NF
CAS Number	9005-38-3
Molecular Formula	$(C_6H_7O_6Na)_n$
Molecular Weight	
MDL Number	
Synonyms	Algin ; Alginic Acid, Sodium Salt

Test	Specification	
	Min	Max
APPEARANCE		
ASSAY (BASED ON A M.W. OF 222.00)	90.8	106.0 %
TOTAL ASH	18.0	27.0 %
LOSS ON DRYING		15.0 %
ARSENIC		1.5 ppm
LEAD		10 ppm
ELEMENTAL IMPURITIES	AS REPORTED	
MICROBIAL LIMITS:		
TOTAL PLATE COUNT		200 cfu/g
SALMONELLA	NEGATIVE	
E.COLI	NEGATIVE	
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION B (1)	VOLUMINOUS,GELATINOUS PRECIPITATE IS FORM IMMEDIATELY	
IDENTIFICATION B (2)	A HEAVY,GELATINOUS PRECIPITATE IS FORM	
IDENTIFICATION C (1)	NO PRECIPITATE IS FORMED	
IDENTIFICATION C (2)	A DENSE PRICIPITATE IS FORMED	
CERTIFIED HALAL		
EXPIRATION DATE		

Test	Specification	
	Min	Max
DATE OF MANUFACTURE		
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 08901	Gardena, CA 90248
732.214.1300	310.516.8000



Certificate Of Analysis

Item Number	S1118	Lot Number	1NA0148
Item	Sodium Alginate, NF	CAS Number	9005-38-3
Molecular Formula	$(C_6H_7O_6Na)_n$		

TF CT	SPECIFICATION		
TEST	MIN	MAX	RESULT
APPEARANCE			WHITE POWDER
ASSAY (BASED ON A M.W. OF 222.00)	90.8	106.0 %	96.06 %
TOTAL ASH	18.0	27.0 %	23.45 %
LOSS ON DRYING		15.0 %	5.0 %
ARSENIC		1.5 ppm	<1.5 ppm
LEAD		10 ppm	<2 ppm
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
MICROBIAL LIMITS:			
TOTAL PLATE COUNT		200 cfu/g	<200 cfu/g
SALMONELLA	NEGATIVE		NEGATIVE
E.COLI	NEGATIVE		NEGATIVE
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION B (1)	VOLUMINOUS,GELATINOUS PRECIPITATE IS FORM IMMEDIATELY		VOLUMINOUS,GELATINOUS PRECIPITATE IS FORM IMMEDIATELY
IDENTIFICATION B (2)	A HEAVY,GELATINOUS PRECIPITATE IS FORM		A HEAVY,GELATINOUS PRECIPITATE IS FORM
IDENTIFICATION C (1)	NO PRECIPITATE IS FORMED		NO PRECIPITATE IS FORMED
IDENTIFICATION C (2)	A DENSE PRICIPITATE IS FORMED		A DENSE PRICIPITATE IS FORMED
CERTIFIED HALAL			CERTIFIED HALAL
EXPIRATION DATE			20-NOV-2025
DATE OF MANUFACTURE			21-NOV-2023

тест	SPECIFICATION		
TEST	MIN	MAX	RESULT
MONOGRAPH EDITION			(USP-NF) 2023
RESIDUAL SOLVENTS		AS REPORTED	
CLASS 3 (solvent) / ETHANOL			<5000 ppm

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 31-JAN-24 17:41:32

Spectrum Chemical Mfg Corp 14422 South San Pedro Street Gardena 90248 CA

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.

The Elemental Impurities standards implemented by USP and other Pharmaceutical Compendia reflect a growing understanding of the toxicology of trace levels of elemental impurities that can remain in drug substances originating from either raw materials or manufacturing processes. Identifying and quantifying impurities can be critical to predicting the best possible patient outcomes. Elemental Impurities has been a requirement of all products meeting USP/NF, EP and BP monographs since January 1, 2018. More information can be found in USP sections <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. Data for drug substances furnished by Spectrum Chemical Mfg. Corp can be used to ensure that patient daily exposures by oral administration to the selected elements are not exceeded in the formulation of pharmaceutical products.

Certificate of Analysis Results Approved By:

AMENDEZ Ana Mendez 05-FEB-24 15:50:05

SAFETY DATA SHEET

Revision date 07-February-2022

1. Identification	
Product identifier	
Product Name	SODIUM ALGINATE, NF
Other means of identification	
Product Code(s)	S1118
Synonyms	None
Recommended use of the chemical	and restrictions on use
Recommended use	or
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 Powder

Physical state Solid

Odor No information available



Revision Number 2

Other information

May be harmful if swallowed.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Sodium Alginate	9005-38-3	100	*

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

4. Fi	t-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 effect	cts, 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	cts Carbon dioxide (CO2). Produce toxic and/or corrosive substances on contact with water.	
Explosion data Sensitivity to mechanical impac	t 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.
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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 propertiesPhysical stateSolidAppearancePowder

Color Odor Odor threshold

Property	Values	Remarks • Method
pH	no data available	None known
Melting point / freezing point	>300 °C / °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	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	no data available	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
Other information_		
Explosive properties	No information available	
Oxidizing properties	No information available	
Softening point	No information available	
Molecular weight	No information available	
VOC Content (%)	No information available	
Liquid Density	No information available	
Dulla develta	N In the forward the second table to	

White to yellowish

No information available

No information available

10. Stability and reactivity

Bulk density

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.

No information available

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	May be harmful if swallowed.

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
Sodium Alginate 9005-38-3	> 5 g/kg (Rat)	-	-

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

Skin corrosion/irritation Serious eye damage/eye irritation Respiratory or skin sensitization Germ cell mutagenicity	No information available. No information available. No information available. No information available.
Reproductive toxicity	No information available.
STOT - single exposure STOT - repeated exposure Aspiration hazard	No information available. No information available. No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

12. Ecological information

Ecotoxicity	The environmental impact of this product has not been fully investigated.
Persistence and degradability Bioaccumulation	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	Does not Comply
ENCS	This product complies with ENCS:
IECSC	This product complies with China:
KECL	Complies
PICCS	Complies
AICS	All the constituents of this material are listed on the Australian Inventory of Chemical
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 TŴĂ 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 07-February-2022 **Revision date**

Revision Note Disclaimer 07-February-2022 No information available.

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

spectrum

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	
S1118	S1118 Sodium Alginate, NF	

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: Spectrum-New Brunswick, NJ: 2020632 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 <u>qualityassurance@spectrumchemical.com</u>

Sincerely,

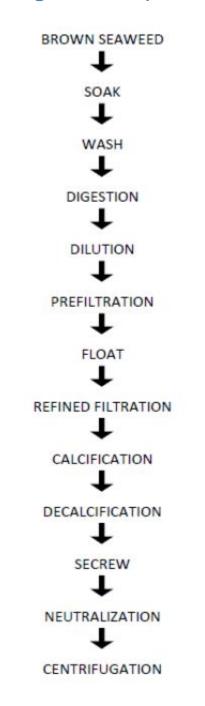
Oulu Umy

Oralia Chavez Quality Assurance Specialist



Manufacturing Process Flowchart

Sodium Alginate, NF (Cat# S1118)



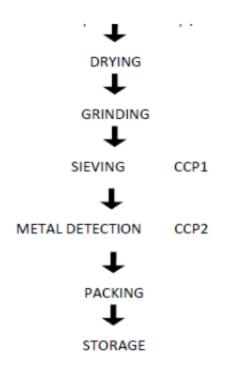
CORPORATE HEADQUARTERS

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

AN ISO 9001:2015 REGISTERED COMPANY





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spectrum

S1118, Sodium Alginate, NF

Source Statement

The above mentioned catalog item is manufactured by plant origin (lessonia flavicans & lessonia nigrescens). 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

- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Soy
- 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 not been tested on animals.

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 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:

Phthalates

• Preservatives

spectrum®

RE: Elemental Impurities - Sodium Alginate, NF (Cat# S1118)

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 <u>TechServices@spectrumchemical.com.</u>

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

AN ISO 9001:2015 REGISTERED COMPANY

spectrum

RE: Residual Solvents - Sodium Alginate, NF (Cat# S1118)

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 the USP <467> Residual Solvents and the ICH Q3C Residual Solvents Guideline. No Class 1, Class 2, Class 3 or other solvents are used or produced in the manufacture of this product.

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 <u>TechServices@spectrumchemical.com</u>.

Sincerely,

Technical Services Spectrum Chemical Mfg. Corp.

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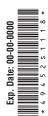
www.spectrumchemical.com

spectrum[®]

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.

s1118 03/20/2019 gm



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



NF

CAS 9005-38-3

CAUTION: For manufacturing, processing or repacking. Read and understand the label and Safety Data

Sheet (SDS) prior to use.

Chemical Emergency: (800)424-9300 www.SpectrumChemical.com

$(C_6H_7O_6Na)_n$

	Assay (Based on a M.W. of 22			
	Total Aab			
Total Ash 18.0-27.0% MAXIMUM LIMITS				
	Loss on Drying			
	Arsenic			
1	Lead			
	Elemental Impurities			
	Microbial Limits	To pass test		
	Residual Solvents	To pass test		

WARNING: Cancer and Reproductive Harmwww.P65Warnings.ca.gov

Lot No. XQ#### G 10/H11GHS 2

Spectrum Chemical Mfg Corp

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