

Scientific Documentation

Chlorobutanol, Hydrous, 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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Specification for Chlorobutanol, Hydrous, NF (CH122)

Item Number	CH122
Item	Chlorobutanol, Hydrous, NF
CAS Number	6001-64-5
Molecular Formula	$C_4H_7Cl_3O \cdot 1/_2H_2O$
Molecular Weight	186.46
MDL Number	
Synonyms	1,1,1-Trichloro-2-methyl-2-propanol

Test	Specification	
	Min	Max
APPEARANCE		
IDENTIFICATION:A	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION: B	RETENTION TIME MATCHES STANDARD	
ASSAY (ANHYDROUS BASIS)	98.0	100.5 %
REACTION (to LITMUS)	NEUTRAL	
WATER DETERMINATION		6.0 %
CHLORIDE (CI)		0.07 %
ELEMENTAL IMPURITIES		AS REPORTED
EXPIRATION DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS	AS REPORTED	
CLASS 2 (solvent) / CHLOROFORM		
CLASS 3 (solvent) / ACETONE		
MONOGRAPH EDITION		

Spectrum Chemical Mfg Corp

769 Jersey Ave. 14422 S. San Pedro St.
New Brunswick, NJ 08901 Gardena, CA 90248

Spectrum Chemical Mfg Corp

Corporate Headquarters: West Coast Facility:

732.214.1300 310.516.8000



Certificate Of Analysis

Item Number	CH122	Lot Number	1MJ0298
Item	Chlorobutanol, Hydrous, NF	CAS Number	6001-64-5
Molecular Formula	$C_4H_7Cl_3O \cdot 1/_2H_2O$	Molecular Weight	186.46

SPECIFICATION TEST			RESULT
IEST	MIN	MAX	RESULI
APPEARANCE			WHITE CRYSTALLINE POWDER
IDENTIFICATION:A	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION: B	RETENTION TIME MATCHES STANDARD		RETENTION TIME MATCHES STANDARD
ASSAY (ANHYDROUS BASIS)	98.0	100.5 %	99.4 %
REACTION (to LITMUS)	NEUTRAL		NEUTRAL
WATER DETERMINATION		6.0 %	4.8 %
CHLORIDE (CI)		0.07 %	<0.07 %
ELEMENTAL IMPURITIES		AS REPORTED	NO ELEMENTAL IMPURITIES PRESENT
EXPIRATION DATE			01-APR-2027
DATE OF MANUFACTURE			17-APR-2022
RESIDUAL SOLVENTS	AS REPORTED		
CLASS 2 (solvent) / CHLOROFORM			<60 ppm
CLASS 3 (solvent) / ACETONE			<5000 ppm
MONOGRAPH EDITION			(USP-NF) 2023

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 07-NOV-23 12:33:02

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



Certificate of Analysis Results Approved By:

SHANSEN Selin Hansen 07-NOV-23 14:01:46

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.

SAFETY DATA SHEET SPECTRUM®



Revision date 14-July-2022 Revision Number 2

1. Identification

Product identifier

Product Name CHLOROBUTANOL, HEMIHYDRATE, NF

Other means of identification

Product Code(s) CH122

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

Acute toxicity - Oral	Category 4
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Specific target organ toxicity (single exposure)	Category 3

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Warning

Hazard statements

Harmful if swallowed Causes skin irritation Causes serious eye irritation May cause respiratory irritation



Appearance Crystals Physical state Solid Odor No information available

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling Do not eat, drink or smoke when using this product

Wear protective gloves/eye protection/face protection

Use only outdoors or in a well-ventilated area Avoid breathing dust/fume/gas/mist/vapors/spray

Precautionary Statements - Response

Specific treatment (see .? on this label)

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

If eye irritation persists: Get medical advice/attention IF ON SKIN: Wash with plenty of water and soap If skin irritation occurs: Get medical advice/attention

Take off contaminated clothing and wash it before reuse

IF INHALED: Remove person to fresh air and keep comfortable for breathing IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell

Rinse mouth

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

No information available.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Chlorobutanol, Hemihydrate	6001-64-5	100	*

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

4. First-aid measures

Description of first aid measures

General advice Show this safety data sheet to the doctor in attendance.

Inhalation Remove to fresh air. Get medical attention immediately if symptoms occur.

Eye contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep

eye wide open while rinsing. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists. Do not rub affected area.

Skin contact Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical

attention if irritation develops and persists.

Ingestion Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water.

Never give anything by mouth to an unconscious person. Call a physician.

Self-protection of the first aider Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

Most important symptoms and effects, both acute and delayed

Symptoms May cause redness and tearing of the eyes. Burning sensation.

Indication of any immediate medical attention and special treatment needed

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. Hydrogen chloride.

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 Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal

protective equipment as required.

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.

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. Avoid contact with

skin, eyes or clothing. Do not eat, drink or smoke when using this product. Take off

contaminated clothing and wash before reuse.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach

of children.

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 If splashes are likely to occur, wear safety glasses with side-shields.

Hand protection Wear suitable gloves. Impervious gloves.

Skin and body protection Wear suitable protective clothing. Long sleeved clothing.

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 Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this

product. Avoid contact with skin, eyes or clothing.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid Appearance Crystals

Color
Odor
Odor
No information available
No information available

Property	Values	Remarks • Method

pН Neutral - Slightly acidic None known Melting point / freezing point 78 °C / 172.4 °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 Very slightly soluble in water None known Solubility(ies) Soluble in Ethanol None known Partition coefficient No data available None known **Autoignition temperature** no data available None known **Decomposition temperature** None known Kinematic viscosityno data availableNone knownDynamic viscosityNo data availableNone known

Other information

Explosive properties

Oxidizing properties

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 Strong acids. Strong bases. Strong oxidizing agents.

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. Irritating to eyes. (based on

components). Causes serious eye irritation.

Skin contact Specific test data for the substance or mixture is not available. Causes skin irritation. (based

on components).

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

gastrointestinal irritation, nausea, vomiting and diarrhea. Harmful if swallowed. (based on

components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Redness. May cause redness and tearing of the eyes.

Acute toxicity

Numerical measures of toxicity

Germ cell mutagenicity

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

Skin corrosion/irritation Class
Serious eye damage/eye irritation
Respiratory or skin sensitization No in

Classification based on data available for ingredients. Irritating to skin.

Classification based on data available for ingredients. Causes serious eye irritation.

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

Chemical name	Algae/aquatic plants	Fish	Toxicity to	Crustacea
			microorganisms	
Chlorobutanol,	-	LC50: =135mg/L (96h,	-	-
Hemihydrate		Pimephales promelas)		
6001-64-5				

Persistence and degradability Bioaccumulation

No information available. Inherently biodegradable.

Component Information

Chemical name	Partition coefficient
Chlorobutanol, Hemihydrate	2.03
6001-64-5	

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

<u>IATA</u> not regulated

IMDG not regulated

RID not regulated

ADR not regulated

ADN 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 Does not Comply EINECS/ELINCS Does not Comply

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

KECL Does not Comply PICCS Does not Comply

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

<u>SARA 313</u>

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 2 Flammability 0 Instability 0

Physical and chemical properties -

HMIS

Health hazards 2
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 14-July-2022

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
CH122	Chlorobutanol, Hydrous, 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: 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



CH122, Chlorobutanol, Hydrous, NF

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

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 is tested on animals only where required for compliance to legal regulations and no accepted alternative methods are available.

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 60 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



RE: Elemental Impurities - Chlorobutanol, Hydrous, NF (Cat# CH122)

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 TechServices@spectrumchemical.com.

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 - Chlorobutanol, Hydrous, NF (Cat# CH122)

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
Chloroform	2	< 60 ppm
Acetone	3	< 5000 ppm

No Class 1 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 TechServices@spectrumchemical.com.

Sincerely,

Technical Services Spectrum Chemical Mfg. Corp.

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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.



• Causes serious eve irritation • Causes skin irritation • Harmful if swallowed • May cause respiratory irritation • May be habit forming. · Do not eat, drink or smoke when using this product

· Wear protective gloves, eye protection, face □ protection • Avoid breathing dust • Use only outdoors ~ or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling.

FIRST AID: Call a POISON CENTER or physician if you feel unwell. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention. IF ON SKIN: Wash with plenty of water. Take off contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth

KEEP FROM CHILDREN

CH122

Chlorobutanol

SIZ SY

(1,1,1-Trichloro-2-methyl-2-propanol)

Hydrous

N.F.

CAS 6001-64-5

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

 $C_4H_7CI_2O^{-1}/_2H_2O$ F.W. 186.46

Assay (Anhydrous Basis)	
Reaction (to Litmus)	Neutral
MAXIMUM LIMIT	S
Water Determination	6.0%
Chloride	0.07%
Elemental Impurities	As reported
Residual Solvents	To pass test

Lot No. XQ#### G 12/G10GHS

Spectrum Chemical Mfg Corp

Corporate Headquarters:

769 Jersey Ave.

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