

# **Scientific Documentation**

# Collodion, USP

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 Collodion, USP (CO120)**

Item Number	CO120
Item	Collodion, USP
CAS Number	9004-70-0
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	

Test	Specificati	on
	Min	Max
APPEARANCE		
ASSAY (PYROXYLIN; by Wt.)	5.0 %	
ALCOHOL DETERMINATION (C <sub>2</sub> H <sub>5</sub> OH)	22.0	26.0 %
SPECIFIC GRAVITY @ 25°C	0.765	0.775
ACIDITY	NOT ACID TO LITMUS	
ELEMENTAL IMPURITIES:		
COBALT (Co)	AS REPORTED	
IDENTIFICATION (A)	BURNS RAPIDLY WITH YELLOW FLAME	
IDENTIFICATION (B)	VISCID, STRINGY MASS IS PRODUCED	
EXPIRATION DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS	AS REPORTED	
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	CO120	Lot Number	1MJ0102
Item	Collodion, USP	CAS Number	9004-70-0

TEST SPECIFICAT		CATION	DESILIT
lesi	MIN	MAX	RESULT
ASSAY (PYROXYLIN; by Wt.)	5.0 %		6.5 %
ALCOHOL DETERMINATION (C <sub>2</sub> H <sub>5</sub> OH)	22.0	26.0 %	24.0 %
SPECIFIC GRAVITY @ 25°C	0.765	0.775	0.773
ACIDITY	NOT ACID TO LITMUS		NOT ACID TO LITMUS
ELEMENTAL IMPURITIES	AS REPORTED		cobalt <1 μg/g
IDENTIFICATION (A)	BURNS RAPIDLY WITH YELLOW FLAME		BURNS RAPIDLY WITH YELLOW FLAME
IDENTIFICATION (B)	VISCID, STRINGY MASS IS PRODUCED		VISCID, STRINGY MASS IS PRODUCED
APPEARANCE			CLEAR COLORLESS LIQUID
EXPIRATION DATE			01-SEP-2024
DATE OF MANUFACTURE			11-SEP-2023
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS PRESENT
MONOGRAPH EDITION			(USP-NF) 2023

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 20-OCT-23 08:03:31

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



Certificate of Analysis Results Approved By:

SHANSEN Selin Hansen 20-OCT-23 09:01:28 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 16-February-2021

**Revision Number** 2

# 1. Identification

**Product identifier** 

Product Name COLLODION, USP

Other means of identification

Product Code(s) CO120

UN/ID no UN2059

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
Reproductive toxicity	Category 1B
Specific target organ toxicity (single exposure)	Category 3
Specific target organ toxicity (repeated exposure)	Category 1
Flammable liquids	Category 1

### Hazards not otherwise classified (HNOC)

Not applicable

# Label elements

Danger

Hazard statements

Harmful if swallowed

Causes skin irritation

Causes serious eye irritation

May damage fertility or the unborn child

May cause respiratory irritation

May cause drowsiness or dizziness

Causes damage to organs through prolonged or repeated exposure

Extremely flammable liquid and vapor



Appearance Clear and viscous

Physical state Liquid

Odor Ethereal

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

Obtain special instructions before use

Do not handle until all safety precautions have been read and understood

Wear protective gloves/protective clothing/eye protection/face protection

Wash face, hands and any exposed skin thoroughly after handling

Do not eat, drink or smoke when using this product

Do not breathe dust/fume/gas/mist/vapors/spray

Use only outdoors or in a well-ventilated area

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking

Keep container tightly closed

Ground/bond container and receiving equipment

Use explosion-proof electrical/ventilating / lighting/ .? / equipment

Use only non-sparking tools

Take precautionary measures against static discharge

Keep cool

## **Precautionary Statements - Response**

IF exposed or concerned: Get medical advice/attention

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 skin irritation occurs: Get medical advice/attention

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower

Wash contaminated clothing 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

In case of fire: Use CO2, dry chemical, or foam to extinguish

#### **Precautionary Statements - Storage**

Store locked up.

Store in a well-ventilated place. Keep container tightly closed

# **Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

# Unknown acute toxicity

0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

#### Other information

Tends to form explosive peroxides when exposed to air and light, and especially when evaporated to dryness.

# 3. Composition/information on ingredients

### **Substance**

Not applicable.

#### <u>Mixture</u>

Chemical name	CAS No	Weight-%	Trade secret
Ethyl Ether	60-29-7	68 - 72	*
Ethanol	64-17-5	23 - 27	*
Pyroxylin	9004-70-0	5	*

<sup>\*</sup>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. IF exposed or concerned: Get medical advice/attention. 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. Do not rub affected area. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

**Skin contact** Wash off immediately with soap and plenty of water while removing all contaminated

clothes and shoes. 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 Remove all sources of ignition. Ensure that medical personnel are aware of the material(s)

involved, take precautions to protect themselves and prevent spread of contamination. Use personal protective equipment as required. See section 8 for more information. Avoid

contact with skin, eyes or clothing.

Most important symptoms and effects, both acute and delayed

**Symptoms** May cause redness and tearing of the eyes. Burning sensation. Inhalation of high vapor

concentrations may cause symptoms like headache, dizziness, tiredness, nausea and

vomiting.

Indication of any immediate medical attention and special treatment needed

**Note to physicians**Treat symptomatically.

# 5. Fire-fighting measures

Suitable Extinguishing Media

Large Fire

Dry chemical. Carbon dioxide (CO2). water spray. Alcohol resistant foam. 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

risk of ignition. Keep product and empty container away from heat and sources of ignition. In the event of fire, cool tanks with water spray. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

**Explosion data** 

Sensitivity to mechanical impact none.

Sensitivity to static discharge yes.

Special protective equipment for fire-fighters

**Personal precautions** 

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

Evacuate personnel to safe areas. Use personal protective equipment as required. See section 8 for more information. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Keep people away from and upwind of spill/leak. ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). Pay attention to flashback. Take precautionary measures against static discharges. All equipment used when handling the

product must be grounded. Do not touch or walk through spilled material.

Other information Ventilate the area. Refer to protective measures listed in Sections 7 and 8.

# Methods and material for containment and cleaning up

Stop leak if you can do it without risk. Do not touch or walk through spilled material. A vapor **Methods for containment** 

suppressing foam may be used to reduce vapors. Dike far ahead of spill to collect runoff water. Keep out of drains, sewers, ditches and waterways. Absorb with earth, sand or other

non-combustible material and transfer to containers for later disposal.

Take precautionary measures against static discharges. Dam up. Soak up with inert Methods for cleaning up

absorbent material. Pick up and transfer to properly labeled containers.

# 7. Handling and storage

#### Precautions for safe handling

Advice on safe handling

Use personal protection equipment. Avoid breathing vapors or mists. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Use grounding and bonding connection when transferring this material to prevent static discharge, fire or explosion. Use with local exhaust ventilation. Use spark-proof tools and explosion-proof equipment. Keep in an area equipped with sprinklers. Use according to package label instructions. 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. Remove contaminated clothing and shoes. Take off contaminated clothing and wash before reuse. In case of insufficient ventilation, wear suitable respiratory equipment.

# Conditions for safe storage, including any incompatibilities

**Storage Conditions** Keep containers tightly closed in a dry, cool and well-ventilated place. Keep at

temperatures below 30°C / 86°F. Keep away from heat, sparks, flame and other sources of ignition (i.e., pilot lights, electric motors and static electricity). Keep in properly labeled containers. Do not store near combustible materials. Keep in an area equipped with sprinklers. Store in accordance with the particular national regulations. Store in accordance

with local regulations. Keep out of the reach of children. Store locked up.

# 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.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Ethyl Ether	No data available	400 ppm TWA	-
60-29-7		1200 mg/m <sup>3</sup> TWA	
Ethanol	No data available	1000 ppm TWA	-
64-17-5		1900 mg/m <sup>3</sup> TWA	

#### Appropriate engineering controls

Engineering controls Showers

Eyewash stations Ventilation systems.

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

**Eye/face protection** Tight sealing safety goggles.

**Hand protection** Wear suitable gloves. Impervious gloves.

**Skin and body protection** Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron.

Antistatic boots.

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** Do not eat, drink or smoke when using this product. Contaminated work clothing should not

be allowed out of the workplace. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product. Wear suitable gloves and eye/face protection. Avoid contact with skin, eyes or clothing.

# 9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Liquid

Appearance Clear and viscous
Color Colorless; light yellow

**Odor** Ethereal

Odor threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

На Neutral None known Melting point / freezing point no data available None known None known 36.1 °C / 97 °F **Boiling point / boiling range** -45 °C / -49 °F None known Flash point None known **Evaporation rate** no data available Flammability (solid, gas) no data available None known Flammability Limit in Air None known

Upper flammability or explosive 36 %

limits

Lower flammability or explosive 1.9 %

limits

Vapor pressureNo data availableNone knownVapor density> 1None knownRelative density0.765 - 0.775None knownWater solubilityVery slightly soluble in cold waterNone known

Water solubilityVery slightly soluble in cold waterNone knownSolubility(ies)no data availableNone knownPartition coefficientNo data availableNone knownAutoignition temperatureno data availableNone knownDecomposition temperatureNone known

Decomposition temperatureNone knownKinematic 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 recommended storage conditions.

Possibility of hazardous reactions 
None under normal processing.

Conditions to avoid Heat, flames and sparks.

**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. May cause drowsiness or dizziness.

**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. Inhalation of high vapor

concentrations may cause symptoms like headache, dizziness, tiredness, nausea and

vomiting.

**Acute toxicity** 

Numerical measures of toxicity

The following values are calculated based on chapter 3.1 of the GHS document

**ATEmix (oral)** 1,608.90 mg/kg **ATEmix (dermal)** 14,200.00 mg/kg

#### Unknown acute toxicity

0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

**Component Information** 

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Ethyl Ether 60-29-7	= 1215 mg/kg (Rat)	= 20 mL/kg (Rabbit) > 20 mL/kg (Rabbit)	= 32000 ppm (Rat) 4 h

Ethanol 64-17-5	= 7060 mg/kg(Rat)	-	124.7 mg/L (Rat)4 h
Pyroxylin	> 5 g/kg (Rat)	-	-
9004-70-0			

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

Skin corrosion/irritation Classification based on data available for ingredients. Irritating to skin.

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

No information available. Respiratory or skin sensitization No information available. Germ cell mutagenicity No information available. Carcinogenicity

The table below indicates whether each agency has listed any ingredient as a carcinogen.

Chemical name	ACGIH	IARC	NTP	OSHA
Ethanol	-	Group 1 - Monograph	-	-
64-17-5		100E [2012] in alcoholic		
		beverages		
		Monograph 96 [2010] in		
		alcoholic beverages		

## Legend

Contains a known or suspected reproductive toxin. Classification based on data available Reproductive toxicity

for ingredients. May damage fertility or the unborn child.

STOT - single exposure May cause respiratory irritation. May cause drowsiness or dizziness. STOT - repeated exposure Causes damage to organs through prolonged or repeated exposure. **Target organ effects** 

liver, respiratory system, Eyes, Skin, central nervous system, blood, Reproductive System.

**Aspiration hazard** No information available. Other adverse effects No information available. No information available. Interactive effects

# 12. Ecological information

**Ecotoxicity** 

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Ethyl Ether	-	LC50: =2560mg/L (96h,	-	EC50: =165mg/L (24h,
60-29-7		Pimephales promelas)		Daphnia magna)
		LC50: >10000mg/L (96h,		
		Lepomis macrochirus)		
Ethanol	-	LC50: 12.0 - 16.0mL/L	-	LC50: 9268 - 14221mg/L
64-17-5		(96h, Oncorhynchus		(48h, Daphnia magna)
		mykiss) LC50: 13400 -		EC50: =10800mg/L (24h,
		15100mg/L (96h,		Daphnia magna) EC50:
		Pimephales promelas)		=2mg/L (48h, Daphnia
		LC50: >100mg/L (96h,		magna)
		Pimephales promelas)		

No information available. Persistence and degradability Bioaccumulation Inherently biodegradable.

**Component Information** 

Chemical name	Partition coefficient
Ethyl Ether 60-29-7	0.82
Ethanol 64-17-5	-0.32

Other adverse effects No information available.

# 13. Disposal considerations

#### Waste treatment methods

Waste from residues/unused

products

Should not be released into the environment. Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Empty containers pose a potential fire and explosion hazard. Do not cut, puncture of weld

containers.

# 14. Transport information

DOT

UN/ID no UN2059

Proper Shipping Name: Nitrocellulose, solution, flammable

Hazard class 3
Packing group:

Special Provisions 198, IB2, T4, TP1, TP8
Marine Pollutant Severe Marine Pollutant

**Description:** UN2059, Nitrocellulose, solution, flammable, 3, II

**Emergency Response Guide** 127

Number

**TDG** 

**UN-No:** UN2059

Proper Shipping Name: Nitrocellulose solution, flammable

Hazard class 3 Packing Group: II

**Description:** UN2059, Nitrocellulose solution, flammable, 3, II

<u>MEX</u>

UN-No UN2059

Proper Shipping Name Nitrocellulose solution, flammable

Hazard class 3
Special Provisions 198
Packing Group II

**Description** UN2059, Nitrocellulose solution, flammable, 3, II

ICAO (air)

**UN-No:** UN2059

Proper Shipping Name: Nitrocellulose solution, flammable

Hazard class 3
Packing Group: 1
Special Provisions A3, A9

**Description:** UN2059, Nitrocellulose solution, flammable, 3, I

<u>IATA</u>

UN number UN2059

Proper Shipping Name: Nitrocellulose solution, flammable

Transport hazard class(es) 3
Packing group | |

**Description:** UN2059, Nitrocellulose solution, flammable, 3, II

MDG

UN number UN2059

Proper shipping name Nitrocellulose solution, flammable

Transport hazard class(es) 3
Packing group II
EmS-No F-E, S-D

Special Provisions 198
Marine pollutant NP1

**Description** UN2059, Nitrocellulose solution, flammable, 3, II, (-45°C c.c.)

RID

UN number UN2059

Proper Shipping Name: Nitrocellulose solution, flammable

Transport hazard class(es) 3
Packing group II
Classification code D

Special Provisions 198, 531, 640C

**Description:** UN2059, Nitrocellulose solution, flammable, 3, II

Labels 3

<u>ADR</u>

UN number 2059

Proper Shipping Name: Nitrocellulose solution, flammable

Transport hazard class(es) 3
Packing group II
Classification code D
Tunnel restriction code (B)

Special Provisions 198, 531, 640C

**Description:** 2059, Nitrocellulose solution, flammable, 3, II, (B)

Labels 3

ADN

UN/ID No UN2059

Proper shipping name Nitrocellulose solution, flammable

Transport hazard class(es) 3
Packing Group II
Classification code D

Special Provisions 198, 531, 640C

**Description** UN2059, Nitrocellulose solution, flammable, 3, II

Hazard label(s) 3
Limited quantity (LQ) 1 L
ventilation VE01
Equipment Requirements PP, EX, A

# 15. Regulatory information

# **International Inventories**

TSCA Complies

DSL/NDSL Complies
EINECS/ELINCS Does not Comply

**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, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302).

Chemical name	Hazardous Substances RQs	Extremely Hazardous Substances RQs
Ethyl Ether	100 lb final RQ	-
60-29-7	45.4 kg final RQ	

# **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 4

Instability 0

Physical and chemical properties -

**HMIS** 

Health hazards 2 \*

Flammability 4

Physical hazards 0

**Personal protection** X Chronic Hazard Star Legend

\* = Chronic Health Hazard

# 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 16-February-2021 Revision Note 16-February-2021 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
CO120	Collodion, USP

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 <a href="mailto:qualityassurance@spectrumchemical.com">qualityassurance@spectrumchemical.com</a>

Sincerely,

Oralia Chavez

**Quality Assurance Specialist** 

Order Clony



# CO120, Collodion, USP

# **Source Statement**

The above mentioned catalog item is manufactured from plant origin (Camphor tree – *Cinnamomum camphora*). 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

# **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.

# **Shelf Life Statement**

The above mentioned catalog item is typically assigned a shelf life of 12 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



# RE: Elemental Impurities – Collodion, USP (Cat# CO120)

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. The following elemental impurities are likely to be present:

Elemental Impurity		Class	Expected Concentration
Cobalt	Co	2A	< 1 ppm

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not 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 - Collodion, USP (Cat# CO120)

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 <a href="mailto:TechServices@spectrumchemical.com">TechServices@spectrumchemical.com</a>.

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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.

#### DANGER Extremely flammable liquid and vapor • Harmful if sv Causes serious eve irritation • Causes skin irritation • May cause respiratory irritation • May cause drowsiness or dizziness • Causes damage to organs through prolonged or repeated exposure • May damage fertility or the unborn child . Tends to form explosive peroxides when exposed to air, light and evaporated to dryness. Obtain special instructions before use • Do not handle until all safety precautions have been read and understood • Keep away from heat, sparks, open flames, hot surfaces . No smoking . Ground container and receiving equipment • Use explosion-proof equipment • Use only non-sparking tools • Take precautionary measures against static discharge Do not eat, drink or smoke when using this product • Wear protective gloves, protective clothing, eye protection, face protection • Do not breathe mist or vapors • 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 (or hair): Take off immediately all contaminated clothing. Rinse skin with water. Wash contaminated clothing before reuse. If skin irritation persists: Get medical attention, IF INHALED: Remove person to fresh air and keep comfortable

for breathing. IF SWALLOWED: Rinse mouth. IN CASE OF FIRE: Use dry chemical, water spray, alcohol-resistant foam or CO<sub>2</sub> to extinguish.

**KEEP FROM CHILDREN** 

0000-00-00

# CO120 SIZ SY Collodion

**USP** 

CAS 9004-70-0

CAUTION: For manufacturing, processing or

Read and understand the label and Safety Data Sheet (SDS) prior to use. DOT: UN2059, Nitrocellulose, solution, 3, PG II

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

Components: Ethyl Ether...... CAS 60-29-7 Assay (Pyroxylin; by Wt.)..... Min. 5.0% Alcohol Determination (C<sub>2</sub>H<sub>5</sub>OH) ...... 22.0-26.0% Specific Gravity @ 25°C ...... 0.765-0.775 MAXIMUM LIMITS .....To pass test Elemental Impurities ...... As reported Residual Solvents ......To pass test Store below 30°C. WARNING: Cancer and Reproductive Harmwww.P65Warnings.ca.gov

Lot No. XQ#### R 8/H3GHS

# Spectrum Chemical Mfg Corp

Corporate Headquarters:

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732.214.1300

New Brunswick, NJ 08901

West Coast Facility:

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