

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 | Specification | |
|--|-------------------------------------|--------|
| | Min | Max |
| APPEARANCE | | |
| ASSAY (PYROXYLIN; by Wt.) | 5.0 % | |
| ALCOHOL DETERMINATION (C ₂ H ₅ 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 | SPECIFICATION | | RESULT |
|--|----------------------------------|--------|----------------------------------|
| | MIN | MAX | |
| ASSAY (PYROXYLIN; by Wt.) | 5.0 % | | 6.5 % |
| ALCOHOL DETERMINATION (C ₂ H ₅ 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.

Mixture

| 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 | * |

*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

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

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

Methods for containment

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

Methods for cleaning up

Take precautionary measures against static discharges. Dam up. Soak up with inert 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 60-29-7 | No data available | 400 ppm TWA 1200 mg/m ³ TWA | - |
| Ethanol 64-17-5 | No data available | 1000 ppm TWA 1900 mg/m ³ 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> |
|---|-------------------------------------|-------------------------|
| pH | Neutral | None known |
| Melting point / freezing point | no data available | None known |
| Boiling point / boiling range | 36.1 °C / 97 °F | None known |
| Flash point | -45 °C / -49 °F | None known |
| Evaporation rate | no data available | None known |
| Flammability (solid, gas) | no data available | None known |
| Flammability Limit in Air | | None known |
| Upper flammability or explosive limits | 36 % | |
| Lower flammability or explosive limits | 1.9 % | |
| Vapor pressure | No data available | None known |
| Vapor density | > 1 | None known |
| Relative density | 0.765 - 0.775 | None known |
| Water solubility | Very slightly soluble in cold 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 |
| Bulk density | 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 9004-70-0 | > 5 g/kg (Rat) | - | - |

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

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

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

Legend

| | |
|---------------------------------|---|
| Reproductive toxicity | Contains a known or suspected reproductive toxin. Classification based on data available 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. |
| Interactive effects | No information available. |

12. Ecological information

Ecotoxicity

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

| | |
|--------------------------------------|---------------------------|
| Persistence and degradability | No information available. |
| 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 or weld containers. |

14. Transport information

DOT

| | |
|--|--|
| UN/ID no | UN2059 |
| Proper Shipping Name: | Nitrocellulose, solution, flammable |
| Hazard class | 3 |
| Packing group: | II |
| Special Provisions | 198, IB2, T4, TP1, TP8 |
| Marine Pollutant | Severe Marine Pollutant |
| Description: | UN2059, Nitrocellulose, solution, flammable, 3, II |
| Emergency Response Guide Number | 127 |

TDG

| | |
|------------------------------|---|
| UN-No: | UN2059 |
| Proper Shipping Name: | Nitrocellulose solution, flammable |
| Hazard class | 3 |
| Packing Group: | II |
| Description: | UN2059, Nitrocellulose solution, flammable, 3, II |

MEX

| | |
|-----------------------------|---|
| 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: | I |
| Special Provisions | A3, A91 |
| Description: | UN2059, Nitrocellulose solution, flammable, 3, I |

IATA

| | |
|-----------------------------------|---|
| UN number | UN2059 |
| Proper Shipping Name: | Nitrocellulose solution, flammable |
| Transport hazard class(es) | 3 |
| Packing group | II |
| Description: | UN2059, Nitrocellulose solution, flammable, 3, II |

IMDG

| | |
|-----------------------------------|---|
| 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 |

ADR

| | |
|----------------------------|--|
| 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 | 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 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 60-29-7 | 100 lb final RQ 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 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 qualityassurance@spectrumchemical.com

Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez
Quality Assurance Specialist

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 TechServices@spectrumchemical.com.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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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. Below you will find a typical label example for this catalog item.

Exp. Date: 00-00-0000



DANGER

- Extremely flammable liquid and vapor • Harmful if swallowed • Causes serious eye 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 CO₂ to extinguish.

KEEP FROM CHILDREN

CO120

SIZ SY

Collodion

USP

CAS 9004-70-0

CAUTION: For manufacturing, processing or repacking.
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

Ethanol..... CAS 64-17-5

Pyroxylin..... CAS 9004-70-0

Assay (Pyroxylin; by Wt.)..... Min. 5.0%

Alcohol Determination (C₂H₅OH)..... 22.0-26.0%

Specific Gravity @ 25°C..... 0.765-0.775

MAXIMUM LIMITS

Acidity.....To pass test

Elemental Impurities..... As reported

Residual Solvents.....To pass test

Store below 30°C.

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

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

Spectrum Chemical Mfg Corp

Corporate Headquarters:

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732.214.1300

West Coast Facility:

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