

## **Scientific Documentation**

## Methylphenidate Hydrochloride (CII), 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 Methylphenidate Hydrochloride (CII), USP (M1600)

Item Number	M1600
Item	Methylphenidate Hydrochloride (CII), USP
CAS Number	298-59-9
Molecular Formula	C <sub>14</sub> H <sub>19</sub> NO <sub>2</sub> •HCl
Molecular Weight	269.77
MDL Number	
Synonyms	Methyl alpha-Phenyl-2-piperidylacetate Hydrochloride

Test	Specification		
	Min	Max	
ASSAY (DRIED BASIS)	98.0	102.0 %	
LOSS ON DRYING		0.5 %	
ORGANIC IMPURITIES (PROCEDURE 2):			
METHYLPHENIDATE RELATED COMPOUND A		0.2 %	
PHENYLACETIC ACID		0.1 %	
(+/-)-ERYTHRO-ISOMER		0.2 %	
ETHYLPHENIDATE		0.1 %	
BIS-METHYLPHENIDATE		0.1 %	
ANY INDIVIDUAL, UNSPECIFIED IMPURITY		0.1 %	
TOTAL IMPURITIES		0.5 %	
RESIDUE ON IGNITION		0.1 %	
ELEMENTAL IMPURITIES:			
PALLADIUM (Pd)	AS REPORTED		
PLATINUM (Pt)	AS REPORTED		
IDENTIFICATION	TO PASS TEST		
RETEST DATE			
DATE OF MANUFACTURE			
APPEARANCE			
RESIDUAL SOLVENTS	TO PASS TEST		

#### 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	M1600	Lot Number	1LJ0528
Item	Methylphenidate Hydrochloride (CII), USP	Manufacturer Lot	21GW721
CAS Number	298-59-9	Manufacturer Code	4772
Molecular Formula	C <sub>14</sub> H <sub>19</sub> NO <sub>2</sub> •HCl	Molecular Weight	269.77

TECT	SPECIF	ICATION	DECLUT
TEST	MIN	MAX	RESULT
ASSAY (DRIED BASIS)	98.0	102.0 %	99.6 %
LOSS ON DRYING		0.5 %	0.1 %
ORGANIC IMPURITIES (PROCEDURE 2):			
METHYLPHENIDATE RELATED COMPOUND A		0.2 %	0.07 %
PHENYLACETIC ACID		0.1 %	<0.05 %
(+/-)-ERYTHRO-ISOMER		0.2 %	<0.05 %
ETHYLPHENIDATE		0.1 %	<0.05 %
BIS-METHYLPHENIDATE		0.1 %	<0.05 %
ANY INDIVIDUAL, UNSPECIFIED IMPURITY		0.1 %	<0.05 %
TOTAL IMPURITIES		0.5 %	0.07 %
RESIDUE ON IGNITION		0.1 %	0.0 %
ELEMENTAL IMPURITIES:			
PALLADIUM (Pd)	AS REPORTED		<0.02 μg/g (M)
PLATINUM (Pt)	AS REPORTED		<0.01 μg/g (M)
IDENTIFICATION	TO PASS TEST		PASSES TEST
RETEST DATE			30-JUN-2025
DATE OF MANUFACTURE			23-JUN-2021
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS	TO PASS TEST		PASSES TEST
CLASS 2 (SOLVENT) / METHANOL			<3000 ppm (M)
CLASS 3 (solvent) / ISOPROPYL ACETATE			<5000 ppm (M)
CLASS 3 (solvent) / 2-PROPANOL			<5000 ppm (M)
OTHER RESIDUAL SOLVENTS: DIMETHYL CARBONATE			<3000 ppm (M)

TECT	SPECIFICATION		DECLUT	
TEST	MIN	MAX	RESULT	
MONOGRAPH EDITION			(USP) 2022	
NOTE:All results reported with (M) are from				
manufacturer certificate of analysis			•	

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 21-APR-23 11:03:18

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



Certificate of Analysis Results Approved By:

JAMAYA Javier Amaya 28-APR-23 13:56:56

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.

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by Noramco, LLC at 500 Swedes Landing Road, Wilmington, Delaware (DE) 19801, United States (USA). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

# SAFETY DATA SHEET SPECTRUM®



Revision date 25-August-2022

**Revision Number** 2

#### 1. Identification

**Product identifier** 

Product Name METHYLPHENIDATE HYDROCHLORIDE (CII), USP

Other means of identification

Product Code(s) M1600

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

#### Hazards not otherwise classified (HNOC)

Not applicable

#### Label elements

Warning

#### Hazard statements

Harmful if swallowed



Appearance Powder or Crystalline Physical state Solid

powder

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

#### **Precautionary Statements - Response**

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
Methylphenidate Hydrochloride	298-59-9	100	*

<sup>\*</sup>The exact percentage (concentration) of composition has been withheld as a trade secret.

#### 4. First-aid measures

#### Description of first aid measures

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

**Inhalation** Remove to fresh air.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a physician.

**Skin contact** Wash skin with soap and water.

**Ingestion** 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.

#### Most important symptoms and effects, both acute and delayed

**Symptoms** No information available.

#### Indication of any immediate medical attention and special treatment needed

#### 5. Fire-fighting measures

surrounding environment.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

**Unsuitable extinguishing media** Do not scatter spilled material with high pressure water streams.

Specific hazards arising from the

chemical

No information available.

**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 Ensure adequate ventilation.

#### Methods and material for containment and cleaning up

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

**Methods for cleaning up** Pick up and transfer to properly labeled containers.

#### 7. Handling and storage

#### Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

#### Conditions for safe storage, including any incompatibilities

Storage Conditions Keep 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** No special protective equipment required.

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

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

**General hygiene considerations** Handle in accordance with good industrial hygiene and safety practice.

#### 9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid

**Appearance** Powder or Crystalline powder

ColorWhite to Off-WhiteOdorNo information availableOdor thresholdNo information available

Property Values Remarks • Method

рH no data available None known 224 °C / 435.2 °F Melting point / freezing point None known Boiling point / boiling range no data available None known Flash point no data available None known **Evaporation rate** no data available None known Flammability (solid, gas) no data available None known Flammability Limit in Air None known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Vapor pressureNo data availableNone knownVapor densityno data availableNone knownRelative densityno data availableNone knownWater solubilitySoluble in waterNone knownSolubility(ies)Soluble in AlcoholNone known

Very slightly soluble in acetone

Slightly soluble in chloroform

 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

 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**None known based on information supplied.

Hazardous decomposition products None known based on information supplied.

#### 11. Toxicological information

#### Information on likely routes of exposure

Product Information

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

**Eye contact** Specific test data for the substance or mixture is not available.

**Skin contact** Specific test data for the substance or mixture is not available.

**Ingestion** Specific test data for the substance or mixture is not available. Harmful if swallowed. (based

on components).

Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** No information available.

**Acute toxicity** 

**Numerical measures of toxicity** 

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Methylphenidate Hydrochloride	= 350 mg/kg (Rat)	-	-
298-59-9			

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

Skin corrosion/irritation
Serious eye damage/eye irritation
Respiratory or skin sensitization
Germ cell mutagenicity

No information available.
No information available.
No information available.

Reproductive toxicity No information available.

STOT - single exposure
STOT - repeated exposure
Aspiration hazard

No information available.
No information available.
No information available.
No information available.

Interactive effects No information available.

#### 12. Ecological information

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

Persistence and degradability Bioaccumulation

No information available. Inherently biodegradable.

Other adverse effects

No information available.

#### 13. Disposal considerations

#### Waste treatment methods

Waste from residues/unused

products

Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

**Contaminated packaging** Do not reuse empty containers.

#### 14. Transport information

**DOT** not regulated

TDG not regulated

MEX not regulated

ICAO (air) not regulated

**IATA** not regulated

IMDG not regulated

RID not regulated

ADR not regulated

<u>ADN</u> 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 Complies EINECS/ELINCS Complies

ENCS This product complies with ENCS:

IECSC This product does not comply 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

#### **US Federal Regulations**

#### **SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

#### SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

#### **CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

#### **CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

#### **US State Regulations**

#### **California Proposition 65**

This product does not contain any Proposition 65 chemicals.

#### U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

#### U.S. EPA Label Information

**EPA Pesticide Registration Number** Not applicable

#### 16. Other information

#### **NFPA**

Health hazards 0 Flammability 0 Instability 0

Physical and chemical properties -

**HMIS** 

Health hazards 0 Flammability 0 Physical hazards 0 Personal protection X

#### Key or legend to abbreviations and acronyms used in the safety data sheet

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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 25-August-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
M1600	Methylphenidate Hydrochloride (CII), 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



## **Manufacturing Process Flowchart**

## Methylphenidate Hydrochloride (CII), USP (Cat# M1600)

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



## M1600, Methylphenidate Hydrochloride (CII), USP

#### **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
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy

- Cereals containing Gluten
- Fish
- 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.

#### **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 48 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 - Methylphenidate Hydrochloride (CII), USP (Cat# M1600)

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
Palladium	Pd	2B	< 0.02 ppm
Platinum	Pt	2B	< 0.01 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 <a href="mailto:TechServices@spectrumchemical.com">TechServices@spectrumchemical.com</a>.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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

CORPORATE HEADQUARTERS

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

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



#### RE: Residual Solvents - Methylphenidate Hydrochloride (CII), USP (Cat# M1600)

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
Methanol	2	< 3000 ppm
Isopropyl Acetate	3	< 5000 ppm
2-Propanol	3	< 5000 ppm
Dimethyl Carbonate		< 3000 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 <a href="mailto:TechServices@spectrumchemical.com">TechServices@spectrumchemical.com</a>.

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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CORPORATE HEADQUARTERS

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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.



M1600 06-29-2019 FV GHS

## **Retest Date Required**

#### Spectrum Chemical Mfg Corp