

Scientific Documentation

Methadone 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 Methadone Hydrochloride (CII), USP (M1426)

Item Number	M1426
Item	Methadone Hydrochloride (CII), USP
CAS Number	1095-90-5
Molecular Formula	C ₂₁ H ₂₇ NO•HCl
Molecular Weight	345.91
MDL Number	
Synonyms	(+/-)-6-Dimethylamino-4,4-diphenylheptan-3-one Hydrochloride ; Amidine Hydrochloride

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.5	100.5 %
pH	4.5	6.5
LOSS ON DRYING		0.3 %
RESIDUE ON IGNITION		0.1 %
ORDINARY IMPURITIES		1.0 %
ELEMENTAL IMPURITIES	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	M1426	Lot Number	1LK0171
Item	Methadone Hydrochloride (CII), USP	Manufacturer Lot	2012000010
CAS Number	1095-90-5	Manufacturer Code	5840
Molecular Formula	C ₂₁ H ₂₇ NO•HCl	Molecular Weight	345.91

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (DRIED BASIS)	98.5	100.5 %	98.8 %
pH	4.5	6.5	5.7 (M)
LOSS ON DRYING		0.3 %	0.2 % (M)
RESIDUE ON IGNITION		0.1 %	0.0 % (M)
ORDINARY IMPURITIES		1.0 %	<1.0 (M)
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD (M)
IDENTIFICATION		TO PASS TEST	PASSES TEST
RETEST DATE			30-NOV-2025
DATE OF MANUFACTURE			01-DEC-2020
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS		TO PASS TEST	PASSES TEST
MONOGRAPH EDITION			(USP) 2022
NOTE: All results reported with (M) are from manufacturer certificate of analysis			

Certificate of Analysis Results Entered By:

DGARCIA
Dylan Garcia
29-NOV-22 10:09:52

Certificate of Analysis Results Approved By:

JAMAYA
Javier Amaya
29-NOV-22 10:10:42

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



All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.

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

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 SpecGx LLC dba Mallinckrodt at 3600 N. 2nd Street, St. Louis, Missouri (MO) 63147, 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 07-October-2022

Revision Number 2

1. Identification

Product identifier

Product Name METHADONE HYDROCHLORIDE (CII), USP

Other means of identification

Product Code(s) M1426

UN/ID no UN2811

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 2
Acute toxicity - Dermal	Category 4
Acute toxicity - Inhalation (Dusts/Mists)	Category 4
Skin sensitization	Category 1A
Reproductive toxicity	Category 2
Specific target organ toxicity (single exposure)	Category 3

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Danger

Hazard statements

Fatal if swallowed

Harmful in contact with skin
Harmful if inhaled
May cause an allergic skin reaction
May cause drowsiness or dizziness
Suspected of damaging fertility or the unborn child



Appearance Crystalline powder

Physical state Solid

Odor No information available

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
Avoid breathing dust/fume/gas/mist/vapors/spray
Use only outdoors or in a well-ventilated area
Contaminated work clothing must not be allowed out of the workplace

Precautionary Statements - Response

IF exposed or concerned: Get medical advice/attention
Specific treatment (see .? on this label)
IF ON SKIN: Wash with plenty of water and soap
Call a POISON CENTER or doctor if you feel unwell
Take off contaminated clothing and wash it before reuse
If skin irritation or rash occurs: Get medical advice/attention
IF INHALED: Remove person to fresh air and keep comfortable for breathing
IF SWALLOWED: Immediately call a POISON CENTER or doctor
Rinse mouth

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

Other information

May be habit forming.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%
Methadone Hydrochloride	1095-90-5	100

4. First-aid measures

Description of first aid measures

General advice	Immediate medical attention is required. Show this safety data sheet to the doctor in attendance.
Inhalation	Remove to fresh air. IF exposed or concerned: Get medical advice/attention. If breathing has stopped, give artificial respiration. Get medical attention immediately. If symptoms persist, call a physician.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Wash with soap and water. May cause an allergic skin reaction. Wash off immediately with plenty of water for at least 15 minutes. If symptoms persist, call a physician.
Ingestion	Get immediate medical advice/attention. Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person.
Self-protection of the first aider	Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Avoid breathing dust/fume/gas/mist/vapors/spray. Use personal protective equipment as required. See section 8 for more information.

Most important symptoms and effects, both acute and delayed

Symptoms Itching. Rashes. Hives. Coughing and/ or wheezing. Difficulty in breathing.

Indication of any immediate medical attention and special treatment needed

Note to physicians May cause sensitization in susceptible persons. Treat symptomatically.

5. Fire-fighting measures

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.
Specific hazards arising from the chemical	Product is or contains a sensitizer. May cause sensitization by skin contact.
Hazardous combustion products	Carbon monoxide. Carbon dioxide (CO ₂). Nitrogen oxides (NO _x). hydrogen chloride gas.
Explosion data	
Sensitivity to mechanical impact	none.
Sensitivity to static discharge	none.
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions	Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak. Avoid generation of dust. Do not breathe dust.
Other information	Refer to protective measures listed in Sections 7 and 8.

Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Pick up and transfer to properly labeled containers.

7. Handling and storage

Precautions for safe handling

Advice on safe handling	Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse. Remove contaminated clothing and shoes. Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid generation of dust.
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Conditions for safe storage, including any incompatibilities

Storage Conditions	Store locked up. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. Air sensitive. Sensitive to light. Store in light-resistant containers.
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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.
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Appropriate engineering controls

Engineering controls	Showers Eyewash stations Ventilation systems.
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Individual protection measures, such as personal protective equipment

Eye/face protection	Wear safety glasses with side shields (or goggles).
Hand protection	Wear suitable gloves.
Skin and body protection	Wear suitable protective clothing. Long sleeved clothing.
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
General hygiene considerations	Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product. Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Avoid breathing dust/fume/gas/mist/vapors/spray.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Solid
Appearance	Crystalline powder
Color	White
Odor	No information available
Odor threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	no data available	None known
Melting point / freezing point	235 °C / 455 °F	None known
Boiling point / boiling range	no data available	None known
Flash point	no data available	None known
Evaporation rate	no data available	None known
Flammability (solid, gas)	no data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	no data available	None known
Water solubility	Soluble in water	None known
Solubility(ies)	Soluble in Ethanol	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
<u>Other information</u>		
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 normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	Excessive heat.
Incompatible materials	Oxidizing or reducing agents. Acids. Bases.
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. Harmful by inhalation. (based on components).
Eye contact	Specific test data for the substance or mixture is not available.

Skin contact

May cause sensitization by skin contact. Specific test data for the substance or mixture is not available. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components). May be absorbed through the skin in harmful amounts. Harmful in contact with skin.

Ingestion

Specific test data for the substance or mixture is not available. Fatal if swallowed. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics**Symptoms**

Itching. Rashes. Hives. Coughing and/ or wheezing.

Acute toxicity**Numerical measures of toxicity**

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Methadone Hydrochloride 1095-90-5	= 30 mg/kg (Rat)	-	-

Delayed and immediate effects as well as chronic effects from short and long-term exposure**Skin corrosion/irritation**

No information available.

Serious eye damage/eye irritation

No information available.

Respiratory or skin sensitization

May cause sensitization by skin contact.

Germ cell mutagenicity

No information available.

Reproductive toxicity

Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. Suspected of damaging fertility or the unborn child.

STOT - single exposure

No information available.

STOT - repeated exposure

No information available.

Aspiration hazard

No information available.

Other adverse effects

No information available.

Interactive effects

No information available.

12. Ecological information**Ecotoxicity**

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

Persistence and degradability

No information available.

Bioaccumulation

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

UN/ID no	UN2811
Proper Shipping Name:	Toxic solids, organic, n.o.s.
Hazard class	6.1
Packing group:	II
Special Provisions	IB8, IP2, IP4, T3, TP33
Marine Pollutant	Severe Marine Pollutant
Description:	UN2811, Toxic solids, organic, n.o.s., 6.1, II
Emergency Response Guide Number	154

TDG

UN-No:	UN2811
Proper Shipping Name:	Toxic solid, organic, n.o.s.
Hazard class	6.1
Packing Group:	II
Special Provisions	16
Description:	UN2811, Toxic solid, organic, n.o.s., 6.1, II

MEX

UN-No	UN2811
Proper Shipping Name	Toxic solid, organic, n.o.s.
Hazard class	6.1
Special Provisions	274
Packing Group	II
Description	UN2811, Toxic solid, organic, n.o.s., 6.1, II

ICAO (air)

UN-No:	UN2811
Proper Shipping Name:	Toxic solid, organic, n.o.s.
Hazard class	6.1
Packing Group:	II
Special Provisions	A3, A5
Description:	UN2811, Toxic solid, organic, n.o.s., 6.1, II

IATA

UN number	UN2811
Proper Shipping Name:	Toxic solid, organic, n.o.s.
Transport hazard class(es)	6.1
Packing group	II
ERG Code	6L
Special Provisions	A3, A5
Description:	UN2811, Toxic solid, organic, n.o.s., 6.1, II

IMDG

UN number	UN2811
Proper shipping name	Toxic solid, organic, n.o.s.
Transport hazard class(es)	6.1
Packing group	II
EmS-No	F-A, S-A
Special Provisions	274
Marine pollutant	NP1
Description	UN2811, Toxic solid, organic, n.o.s., 6.1, II

RID

UN number	UN2811
Proper Shipping Name:	TOXIC SOLID, ORGANIC, N.O.S.
Transport hazard class(es)	6.1
Packing group	II
Classification code	T2
Special Provisions	274, 614
Description:	UN2811, TOXIC SOLID, ORGANIC, N.O.S., 6.1, II
Labels	6.1

ADR

UN number	UN2811
Proper Shipping Name:	Toxic solid, organic, n.o.s.
Transport hazard class(es)	6.1
Packing group	II
Classification code	T2
Tunnel restriction code	(D/E)
Special Provisions	274, 614
Description:	UN2811, Toxic solid, organic, n.o.s., 6.1, II, (D/E)
Labels	6.1

ADN

UN/ID No	UN2811
Proper shipping name	Toxic solid, organic, n.o.s.
Transport hazard class(es)	6.1
Packing Group	II
Classification code	T2
Special Provisions	274, 614, 802
Description	UN2811, Toxic solid, organic, n.o.s., 6.1, II
Hazard label(s)	6.1
Limited quantity (LQ)	500 g
Equipment Requirements	PP, EP

15. Regulatory information**International Inventories**

TSCA Not listed

Note *Contact supplier for details. One or more substances in this product are either not listed on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise exempted from inventory listing requirements

DSL/NDSL	Does not Comply
EINECS/ELINCS	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

PICCS - Philippines Inventory of Chemicals and Chemical Substances

US Federal Regulations**SARA 313**

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

SARA 311/312 Hazard Categories

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

CWA (Clean Water Act)

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

CERCLA

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

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

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

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA

Health hazards 2

Flammability 0

Instability 0

Physical and chemical properties -

HMIS

Health hazards 2 *

Flammability 0

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) (AELG(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 07-October-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
M1426	Methadone 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:

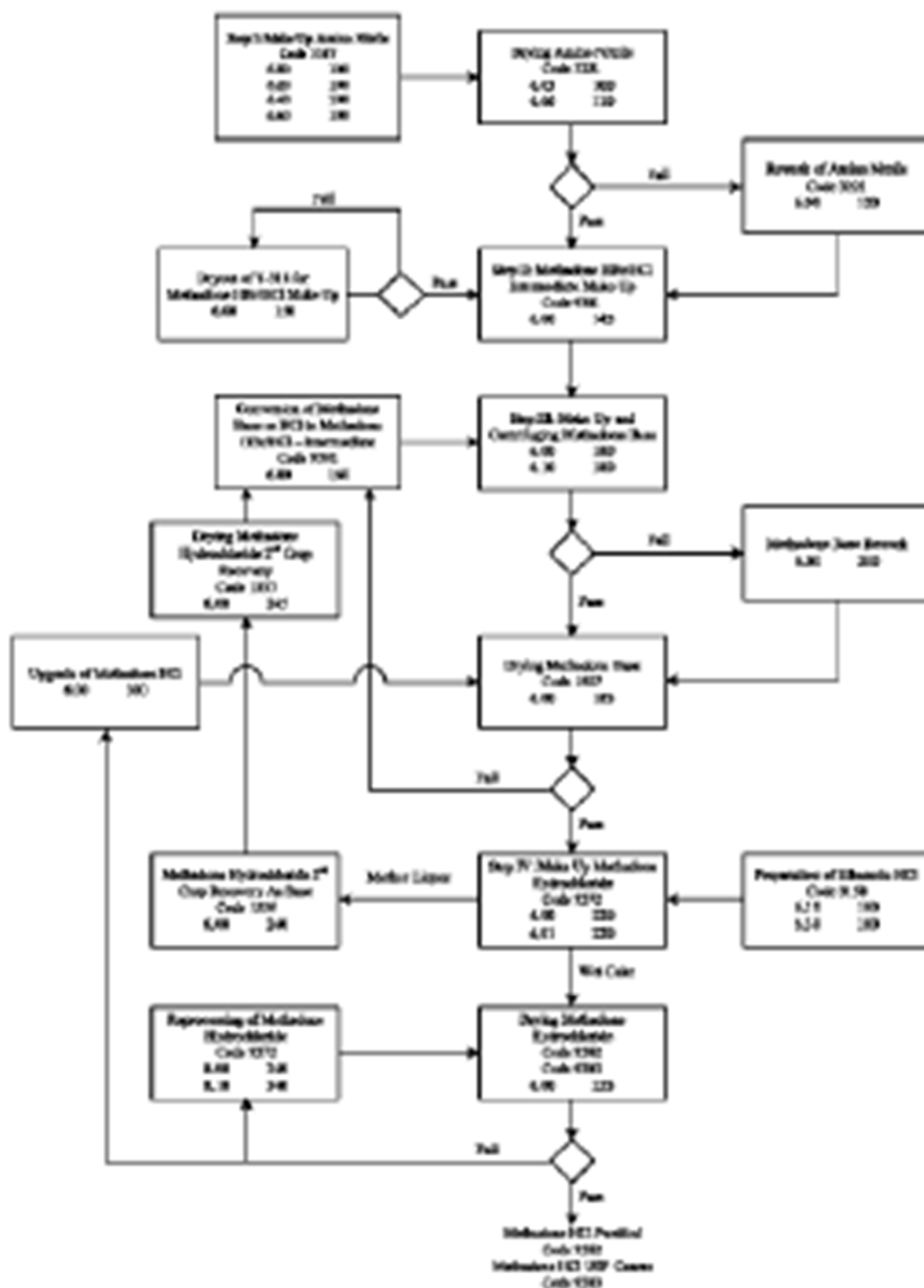
Spectrum-Gardena, CA:	2020632
Spectrum-New Brunswick, NJ:	2246824

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 qualityassurance@spectrumchemical.com

Sincerely,
Quality Assurance
Spectrum Chemical Mfg. Corp.

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

Manufacturing Process Flowchart - Methadone Hydrochloride (CII), USP (Catalog No. M1426)



Methadone HCL Purified, Code
0382



Methadone Hydrochloride USP Powder, Code 1510

Elemental Impurities - Methadone Hydrochloride (CII), USP (Catalog No. M1426)

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
Cadmium	Cd	1	< 0.2 ppm
Lead	Pb	1	< 0.2 ppm
Arsenic	As	1	< 0.6 ppm
Cobalt	Co	2A	< 2.0 ppm
Vanadium	V	2A	< 4.0 ppm
Nickel	Ni	2A	< 8.0 ppm
Selenium	Se	2B	< 6.0 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 the 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.

Residual Solvents - Methadone Hydrochloride (CII), USP (Catalog No. M1426)

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
Ethanol	3	< 5000 ppm

No Class 1 or other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at TechServices@spectrumchemical.com.

Sincerely,
Technical Services
Spectrum Chemical Mfg. Corp.

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

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

- Fatal if swallowed • Harmful in contact with skin or if inhaled • May cause an allergic skin reaction • May cause drowsiness or dizziness • Suspected of damaging fertility or the unborn child • May be habit forming.
- Obtain special instructions before use • Do not handle until all safety precautions have been read and understood • Do not eat, drink or smoke when using this product • Wear protective gloves, protective clothing, eye protection, face protection • Avoid breathing dust • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling • Contaminated work clothing must not be allowed out of the workplace.
- FIRST AID:** Immediately call a POISON CENTER or physician. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention. IF ON SKIN: Wash with plenty of water. Take off contaminated clothing and wash it before reuse. IF skin irritation or rash occurs: Get medical attention. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth.

KEEP FROM CHILDREN

M1426

Methadone Hydrochloride

USP

CAS 1095-90-5

CAUTION: For manufacturing, processing, repacking, or for prescription compounding. Rx only.
Read and understand the label and Safety Data Sheet (SDS) prior to use.

DOT: UN2811, Toxic solid, organic, n.o.s. (methadone hydrochloride), 6.1, PG II

Chemical Emergency: (800)424-9300

www.SpectrumChemical.com

SIZ SY

$C_{21}H_{27}NO \cdot HCl$ F.W. 345.91

DEA Number Required.

Manufacturer/Supplier Code ?
 Manufacturer Lot Number ?
 Assay (Dried Basis) 98.5-100.5%
 pH 4.5-6.5

MAXIMUM LIMITS

Loss on Drying 0.3%
 Residue on Ignition 0.1%
 Ordinary Impurities 1.0%
 Elemental Impurities As reported
 Residual Solvents To pass test
LIGHT SENSITIVE, AIR SENSITIVE: Keep tightly closed in light-resistant containers.

Repackaged by Spectrum as:
 B 6/17GHS-A ? Lot No. XQ####

Spectrum Chemical Mfg Corp

Corporate Headquarters:

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