

# Scientific Documentation

## Hydromorphone Hydrochloride (CII), USP

Not appropriate for regulatory submission.

Please visit [www.spectrumchemical.com](http://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



## **Table of Contents**

Product Specification  
Certificate of Analysis  
Safety Data Sheet (SDS)  
Certification of Current Good Manufacturing Practices (cGMP)  
Manufacturing Process Flowchart  
Technical Statements  
Elemental Impurities Statement  
Residual Solvents Statement  
General Label Information – Sample Label

# Specification for Hydromorphone Hydrochloride (CII), USP (H1107)

Item Number	H1107
Item	Hydromorphone Hydrochloride (CII), USP
CAS Number	71-68-1
Molecular Formula	C <sub>17</sub> H <sub>19</sub> NO <sub>3</sub> •HCl
Molecular Weight	321.80
MDL Number	
Synonyms	Dihydromorphinone Hydrochloride ; 6-Deoxy-7,8-dihydro-6-oxomorphine Hydrochloride

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.0	101.0 %
SPECIFIC ROTATION [α] <sub>D</sub>	-136° to -139°	
ACIDITY		TO PASS TEST
LOSS ON DRYING		1.5 %
RESIDUE ON IGNITION		0.3 %
ORGANIC IMPURITIES		TO PASS TEST
ELEMENTAL IMPURITIES	AS REPORTED	
IDENTIFICATION		TO PASS TEST
APPEARANCE		
RETEST DATE		
DATE OF MANUFACTURE		
RESIDUAL SOLVENTS	AS REPORTED	
CLASS 2 (solvent) / ACETONITRILE	.	
CLASS 2 (SOLVENT) / METHANOL	.	
CLASS 3 (solvent) / ETHANOL	.	
MONOGRAPH EDITION		

*Spectrum Chemical Mfg Corp*

**Corporate Headquarters:** West Coast Facility:  
769 Jersey Ave. 14422 S. San Pedro St.

***Spectrum Chemical Mfg Corp***

---

***Corporate Headquarters:***    ***West Coast Facility:***

New Brunswick, NJ 08901    Gardena, CA 90248

732.214.1300

310.516.8000

## Certificate Of Analysis

Item Number	H1107	Lot Number	1MH0176
Item	Hydromorphone Hydrochloride (CII), USP	Manufacturer Lot	22HW326
CAS Number	71-68-1	Manufacturer Code	4772
Molecular Formula	C <sub>17</sub> H <sub>19</sub> NO <sub>3</sub> •HCl	Molecular Weight	321.80

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (DRIED BASIS)	98.0	101.0 %	99.7 %
SPECIFIC ROTATION [α] <sub>D</sub>	-136° to -139°		-138°
ACIDITY		TO PASS TEST	PASSES TEST
LOSS ON DRYING		1.5 %	0.2 %
RESIDUE ON IGNITION		0.3 %	0.1 %
ORGANIC IMPURITIES		TO PASS TEST	PASSES TEST
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
IDENTIFICATION		TO PASS TEST	PASSES TEST
APPEARANCE			WHITE POWDER
RETEST DATE			31-JUL-2026
DATE OF MANUFACTURE			08-JUL-2022
RESIDUAL SOLVENTS	AS REPORTED		.
CLASS 2 (solvent) / ACETONITRILE	.		<410 ppm
CLASS 2 (SOLVENT) / METHANOL	.		<3000 ppm
CLASS 3 (solvent) / ETHANOL	.		<5000 ppm
MONOGRAPH EDITION			(USP-NF) 2023

Certificate of Analysis Results Entered By:

HBERMUDEZ  
Hernan Bermudez  
26-OCT-23 07:56:15

Certificate of Analysis Results Approved By:

SHANSEN  
Selin Hansen  
27-OCT-23 12:26:03

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 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 12-September-2022

Revision Number 2

## 1. Identification

### Product identifier

**Product Name** HYDROMORPHONE HYDROCHLORIDE (CII), USP

### Other means of identification

**Product Code(s)** H1107

**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
Specific target organ toxicity (single exposure)	Category 3

### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

#### Warning

#### Hazard statements

Harmful if swallowed  
May cause drowsiness or dizziness



**Appearance** Crystalline powder or powder

**Physical state** Solid

**Odor** No information available

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

Wash face, hands and any exposed skin thoroughly after handling  
Do not eat, drink or smoke when using this product  
Avoid breathing dust/fume/gas/mist/vapors/spray  
Use only outdoors or in a well-ventilated area

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

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

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

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

#### **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-%	Trade secret
Hydromorphone Hydrochloride	71-68-1	100	*

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

### **4. First-aid measures**

#### **Description of first aid measures**

<b>General advice</b>	Show this safety data sheet to the doctor in attendance.
<b>Inhalation</b>	Remove to fresh air. IF exposed or concerned: Get medical advice/attention.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Wash skin with soap and water.
<b>Ingestion</b>	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**

**Note to physicians** 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** No information available.

**Hazardous combustion products** carbon oxides. Nitrogen oxides (NO<sub>x</sub>).

**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. Use personal protective equipment as required. Evacuate personnel to safe areas.

**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.

**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.

**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** 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** Crystalline powder or powder  
**Color** White  
**Odor** No information available  
**Odor threshold** No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>pH</b>	no data available	None known
<b>Melting point / freezing point</b>	> 280 °C / 536 °F	None known
<b>Boiling point / boiling range</b>	no data available	None known
<b>Flash point</b>	no data available	None known
<b>Evaporation rate</b>	no data available	None known
<b>Flammability (solid, gas)</b>	no data available	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability or explosive limits</b>	No data available	
<b>Lower flammability or explosive limits</b>	No data available	
<b>Vapor pressure</b>	No data available	None known
<b>Vapor density</b>	no data available	None known
<b>Relative density</b>	no data available	None known
<b>Water solubility</b>	Soluble in water	None known
<b>Solubility(ies)</b>	Very slightly soluble in Ethanol Practically insoluble in Chloroform Practically insoluble in Ether Slightly soluble in Dimethyl sulfoxide (DMSO)	None known
<b>Partition coefficient</b>	No data available	None known
<b>Autoignition temperature</b>	no data available	None known
<b>Decomposition temperature</b>		None known
<b>Kinematic viscosity</b>	no data available	None known
<b>Dynamic viscosity</b>	No data available	None known

#### Other information

**Explosive properties** No information available

<b>Oxidizing properties</b>	No information available
<b>Softening point</b>	No information available
<b>Molecular weight</b>	No information available
<b>VOC Content (%)</b>	No information available
<b>Liquid Density</b>	No information available
<b>Bulk density</b>	No information available

## 10. Stability and reactivity

<b>Reactivity</b>	No information available.
<b>Chemical stability</b>	Stable under normal conditions.
<b>Possibility of hazardous reactions</b>	None under normal processing.
<b>Conditions to avoid</b>	None known based on information supplied.
<b>Incompatible materials</b>	None known based on information supplied.
<b>Hazardous decomposition products</b>	None known based on information supplied.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Product Information</b>	.
<b>Inhalation</b>	Specific test data for the substance or mixture is not available.
<b>Eye contact</b>	Specific test data for the substance or mixture is not available.
<b>Skin contact</b>	Specific test data for the substance or mixture is not available.
<b>Ingestion</b>	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

<b>Symptoms</b>	No information available.
-----------------	---------------------------

### Acute toxicity

<b>Numerical measures of toxicity</b>
No information available

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

<b>Skin corrosion/irritation</b>	No information available.
<b>Serious eye damage/eye irritation</b>	No information available.
<b>Respiratory or skin sensitization</b>	No information available.
<b>Germ cell mutagenicity</b>	No information available.
<b>Reproductive toxicity</b>	No information available.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	No information available.
<b>Aspiration hazard</b>	No information available.
<b>Other adverse effects</b>	No information available.
<b>Interactive effects</b>	No information available.

## 12. Ecological information

<b>Ecotoxicity</b>	The environmental impact of this product has not been fully investigated.
<b>Persistence and degradability</b> <b>Bioaccumulation</b>	No information available. Inherently biodegradable.
<b>Other adverse effects</b>	No information available.

## 13. Disposal considerations

### Waste treatment methods

<b>Waste from residues/unused products</b>	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
<b>Contaminated packaging</b>	Do not reuse empty containers.

## 14. Transport information

<b><u>DOT</u></b>	not regulated
<b><u>TDG</u></b>	not regulated
<b><u>MEX</u></b>	not regulated
<b><u>ICAO (air)</u></b>	not regulated
<b><u>IATA</u></b>	not regulated
<b><u>IMDG</u></b>	not regulated
<b><u>RID</u></b>	not regulated
<b><u>ADR</u></b>	not regulated
<b><u>ADN</u></b>	not regulated

## 15. Regulatory information

### International Inventories

<b>TSCA</b>	Not listed
<b>Note</b>	*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
<b>DSL/NDSL</b>	Complies
<b>EINECS/ELINCS</b>	Complies
<b>ENCS</b>	This product complies with ENCS:
<b>IECSC</b>	This product does not comply with china:
<b>KECL</b>	Does not Comply
<b>PICCS</b>	Does not Comply
<b>AICS</b>	This product does not comply with 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** 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) (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

<b>Revision date</b>	12-September-2022
<b>Revision Note</b>	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
H1107	Hydromorphone 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

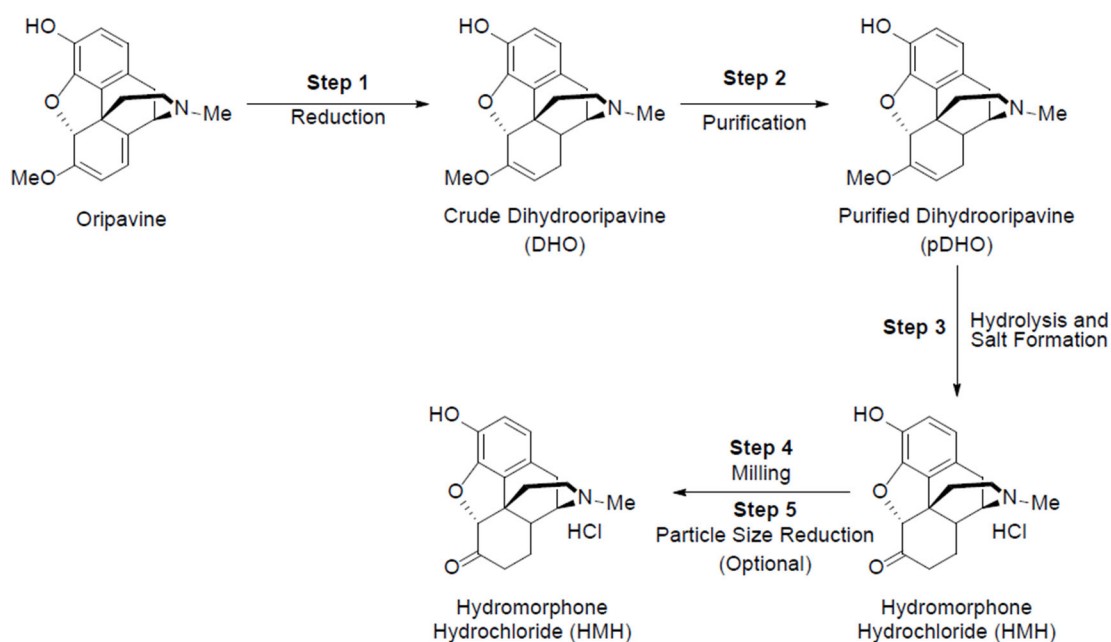
Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com)

Sincerely,

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

Oralia Chavez  
Quality Assurance Specialist

## Manufacturing Process Flowchart Hydromorphone Hydrochloride (CII), USP (Cat# H1107)



### 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



## H1107, Hydromorphone 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
- 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.

## 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 36 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        | • Parabens      |
| • Antibiotics       | • Pesticides    |
| • Bisphenol A (BPA) | • Phthalates    |
| • CMR Substances    | • Preservatives |



**RE: Elemental Impurities - Hydromorphone Hydrochloride (CII), USP (Cat# H1107)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at [TechServices@spectrumchemical.com](mailto: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 - Hydromorphone Hydrochloride (CII), USP (Cat# H1107)**

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
Acetonitrile	2	< 410 ppm
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](mailto: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

## 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.

**WARNING**  
 • Harmful if swallowed • May cause drowsiness or dizziness • May be habit forming.  
 • Do not eat, drink or smoke when using this product • Avoid breathing dust • Use only outdoors or in a well-ventilated area • Wash face, hands and any exposed skin thoroughly after handling.  
**FIRST AID:** Call a POISON CENTER or physician if you feel unwell. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF SWALLOWED: Rinse mouth.  
**KEEP FROM CHILDREN**

**H1107      SIZ SY**  
**Hydromorphone**  
**Hydrochloride**  
 (Dihydromorphinone Hydrochloride)  
 USP  
 CAS 71-68-1

**C<sub>17</sub>H<sub>19</sub>NO<sub>3</sub>•HCl      F.W. 321.80**

DEA Number Required. \_\_\_\_\_  
 Manufacturer/Supplier Code \_\_\_\_\_?  
 Manufacturer Lot Number \_\_\_\_\_?  
 Assay (Dried Basis) \_\_\_\_\_ 98.0-102.0%  
 Specific Rotation, [α]<sub>D</sub><sup>25</sup> \_\_\_\_\_ -136° to -139°  
 Acidity \_\_\_\_\_ To pass test  
 Loss on Drying \_\_\_\_\_ 1.5%  
 Residue on Ignition \_\_\_\_\_ 0.3%  
 Organic Impurities:  
   8-Hydroxyhydromorphone \_\_\_\_\_ 0.15%  
   Dihydromorphine (DHM) \_\_\_\_\_ 0.5%  
   Morphine \_\_\_\_\_ 0.15%  
   Hydromorphone N-Oxide \_\_\_\_\_ 0.15%  
   Hydromorphone Related Compound A \_\_\_\_\_ 0.1%  
   8,14-Dihydrooripavine \_\_\_\_\_ 0.15%  
   6β-Tetrahydrooripavine \_\_\_\_\_ 0.15%  
   2,2'-Bishydromorphine \_\_\_\_\_ 0.15%  
   Individual Unspecified Impurities \_\_\_\_\_ 0.1%  
   Total Impurities \_\_\_\_\_ 1.0%  
   Elemental Impurities \_\_\_\_\_ As reported  
   Residual Solvents \_\_\_\_\_ To pass test

LIGHT SENSITIVE: Keep tightly closed in light-resistant containers.

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

**Chemical Emergency: (800)424-9300**  
[www.SpectrumChemical.com](http://www.SpectrumChemical.com)

Repackaged by Spectrum as:  
 Lot No. XQ####

### Spectrum Chemical Mfg Corp

#### Corporate Headquarters:

769 Jersey Ave.  
 New Brunswick, NJ 08901  
 732.214.1300

#### West Coast Facility:

14422 S. San Pedro St.  
 Gardena, CA 90248  
 310.516.8000