

Scientific Documentation

Cocaine 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





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 Cocaine Hydrochloride (CII), USP (C1408)

Item Number	C1408
Item	Cocaine Hydrochloride (CII), USP
CAS Number	53-21-4
Molecular Formula	C ₁₇ H ₂₁ NO ₄ •HCl
Molecular Weight	339.81
MDL Number	
Synonyms	

Test	Specification		
	Min	Max	
ASSAY (DRIED BASIS)	99.0	101.0 %	
SPECIFIC ROTATION [a] _D	-71 to -73		
ACIDITY		0.5 ml	
LOSS ON DRYING		1.0 %	
RESIDUE ON IGNITION		0.1 %	
READILY CARBONIZABLE SUBSTANCES	MATCHING FLUID F		
CINNAMYL-COCAINE AND OTHER[nREDUCING SUBSTANCES	VIOLET COLOR REMAINS		
ISOATROPYL-COCAINE	CRYSTALLINE PRECIPITATE FORMS/SUPPLEMENT IS CLEAR		
ELEMENTAL IMPURITIES	AS REPORTED		
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES STANDARD		
IDENTIFICATION (B)	ORANGE RED CRYSTALLINE PRECIPITATE FORMS		
IDENTIFICATION (C)	VIOLET CRYSTALLINE PRECIPITATE FORMS		
IDENTIFICATION (D)	POSITIVE FOR CHLORIDE		
RETEST DATE			
DATE OF MANUFACTURE			
APPEARANCE			
RESIDUAL SOLVENTS	AS REPORTED		

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	C1408	Lot Number	1EJ0273
Item	Cocaine Hydrochloride (CII), USP	CAS Number	53-21-4
Molecular Formula	C ₁₇ H ₂₁ NO ₄ •HCl	Molecular Weight	339.81

TECT	SPECIFI	CATION	DECLILT
TEST	MIN	MAX	RESULT
ASSAY (DRIED BASIS)	99.0- 101.0 %		99.2 %
SPECIFIC ROTATION [a] _D	-71 to -73		-72
ACIDITY	TO PASS TEST		PASSES TEST
LOSS ON DRYING		1.0 %	0.1 %
RESIDUE ON IGNITION		0.1 %	0.0 %
READILY CARBONIZABLE SUBSTANCES	TO PASS TEST		PASSES TEST
CINNAMYL-COCAINE AND OTHER[nREDUCING SUBSTANCES	TO PASS TEST		PASSES TEST
ISOATROPYL-COCAINE	TO PASS TEST		PASSES TEST
IDENTIFICATION	TO PASS TEST		PASSES TEST
RETEST DATE			31-MAR-2017
DATE OF MANUFACTURE			21-NOV-2014
APPEARANCE			WHITE POWDER

Certificate of Analysis Results Entered By:

LCASABAR Lilian Casabar 22-OCT-15 15:46:10

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



Certificate of Analysis Results Approved By:

LCASABAR Lilian Casabar 22-OCT-15 15:46:33

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.





SAFETY DATA SHEET

Preparation Date: 7/1/2016 Revision Date: 7/1/2016 Revision Number: G1

1. IDENTIFICATION

Product identifier

Product code: C1408

Product Name: COCAINE HYDROCHLORIDE (CII), USP

Other means of identification

Synonyms: Methyl 3-beta-hydroxy-1-alpha-H,5-alpha-H-tropan-2-beta-carboxylate, benzoate

(ester) HCI

1-alpha-H,5-alpha-H-Tropane-2-beta-carboxylic acid, 3-beta-hydroxy-, methyl

ester, benzoate (ester), hydrochloride

CAS #: 53-21-4
RTECS # YM3050000
CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use:Uses advised against
No information available.
No information available.

Supplier: Spectrum Chemical Mfg. Corp

14422 South San Pedro St.

Gardena, CA 90248 (310) 516-8000

Order Online At: https://www.spectrumchemical.com

Emergency telephone numberChemtrec 1-800-424-9300Contact Person:Martin LaBenz (West Coast)Contact Person:Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Considered a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Acute toxicity - Oral	Category 3
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Skin sensitization	Category 1
Reproductive toxicity	Category 1B
Specific target organ toxicity (single exposure)	Category 3

Label elements

Product code: C1408 Product name: COCAINE 1/12

HYDROCHLORIDE (CII), USP

Danger

Hazard statements

Toxic if swallowed Causes skin irritation Causes serious eye irritation May cause an allergic skin reaction

May cause drowsiness or dizziness

May damage fertility or the unborn child



Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

Precautionary Statements - Prevention

Obtain special instructions before use

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

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

Contaminated work clothing must not be allowed out of the workplace

Use only outdoors or in a well-ventilated area

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

Precautionary Statements - Response

IF exposed or concerned: Get medical advice/attention

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 ON SKIN: Wash with plenty of water

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/physician

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Product code: C1408 Product name: COCAINE 2/12

HYDROCHLORIDE (CII), USP

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Cocaine Hydrochloride	53-21-4	100
53-21-4		

4. FIRST AID MEASURES

First aid measures

General Advice: National Capital Poison Center in the United States can provide assistance if you

have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222. Ensure that medical personnel are aware of the material(s) involved and take

precautions to protect themselves. First aider needs to protect himself.

Skin Contact: Wash off immediately with soap and plenty of water removing all contaminated clothing and

shoes. Get medical attention. If skin irritation persists, call a physician.

Eye Contact: Flush eyes with water for 15 minutes. Get medical attention.

Inhalation: Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

WARNING! It may be hazardous to the person providing aid to give mouth-to-mouth resuscitation when the inhaled or ingested material is toxic, infectious or corrosive. Do not use mouth-to-mouth resuscitation if victim ingested or inhaled the substance; induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper

respiratory medical device. Get medical attention.

Ingestion: Toxic if swallowed. Do not induce vomiting without medical advice. Never give anything by

mouth to an unconscious person. Immediate medical attention is required. Call a physician or

Poison Control Center immediately.

Most important symptoms and effects, both acute and delayed

Symptoms Toxic if swallowed. Central nervous system effects. May cause eye/skin irritation. May cause

an allergic skin reaction.

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically

Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste

5. FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Dry chemical. Carbon dioxide (CO2). Water spray mist or

foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products: carbon monoxide; nitrogen oxides; hydrogen chloride

Specific hazards: May be combustible at high temperatures

Special Protective Actions for Firefighters

Specific Methods: No information available.

Product code: C1408 Product name: COCAINE 3 / 12
HYDROCHLORIDE (CII), USP

Special Protective Equipment for Firefighters:

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Do not touch

damaged containers or spilled material unless wearing appropriate protective clothing. Avoid contact with skin, eyes and clothing. Use personal protective equipment. Remove all sources

of ignition.

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent product from entering

drains. Prevent from entering into soil, ditches, sewers, waterways, and/or ground

water.

Methods and material for containment and cleaning up

Methods for containmentStop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up

Sweep up and shovel into suitable containers for disposal. Clean contaminated

surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not ingest. Do not breathe vapors/dust. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Protect from light. Sensitive to light. Store in light-resistant containers. Store away from incompatible materials.

Incompatible Materials:

Oxidizing agents. Strong acids. Nitrates. iodides. Mercuric oxide. tannins. calomel. Soluble silver salts. Alkalis.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	OSHA	NIOSH	ACGIH	AIHA WHEEL
Cocaine Hydrochloride	None	None	None	None
53-21-4				

Canada

Components Alberta British Columbia Ontario Quebec					
	Components	Alberta	British Columbia	Ontario	Quebec

Product code: C1408 Product name: COCAINE 4 / 12
HYDROCHLORIDE (CII), USP

Cocaine Hydrochloride	None	None	None	None
53-21-4				

Australia and Mexico

Components	Australia	Mexico
Cocaine Hydrochloride	None	None
53-21-4		

Appropriate engineering controls

Engineering measures to reduce exposure:

Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Product code: C1408

Eye protection: Goggles

Skin and body protection: Long sleeved clothing. Chemical resistant apron. Gloves.

Respiratory protection: Wear respirator with dust filter.

Hygiene measures: Avoid contact with skin, eyes and clothing. Wash hands before breaks and

immediately after handling the product. When using, do not eat, drink or smoke.

9. PHYSICAL AND CHEMICAL PROPERTIES

Product name: COCAINE HYDROCHLORIDE (CII), USP 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Appearance: Color:

Solid Crystals. Crystalline powder. Colorless. White.

Odor: Taste Formula:

Odorless. No information available C17H21NO4.HCl

Molecular/Formula weight: Flammability: Flashpoint (°C/°F):

Not flammable No information available.

Flash Point Tested according to: Autoignition Temperature (°C/°F): Lower Explosion Limit (%):

Not available No information available No information available

Upper Explosion Limit (%): Melting point/range(°C/°F): Decomposition temperature(°C/°F):

No information available 195 °C/383 °F No information available

Boiling point/range(°C/°F): Bulk density: Density (g/cm3):

No information available
No information available
No information available

Specific gravity: pH: Vapor pressure @ 20°C (kPa):

No information available
No information available
No information available

Evaporation rate: Vapor density: VOC content (g/L):
No information available

No information available

Odor threshold (ppm): Partition coefficient Viscosity:

No information available (n-octanol/water): No information available

No information available

Miscibility:Solubility:No information availableSoluble in Water

10. STABILITY AND REACTIVITY

Reactivity

No information available

Chemical stability

Stability: Stable under recommended storage conditions

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Exposure to light. Avoid dust formation. Incompatible materials.

Incompatible Materials: Oxidizing agents. Strong acids. Nitrates. iodides. Mercuric oxide. tannins. calomel.

Soluble silver salts. Alkalis.

Hazardous decomposition products: No information available

Other Information

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product code: C1408 Product name: COCAINE 6 / 12
HYDROCHLORIDE (CII), USP

Principal Routes of Exposure:

Ingestion. Inhalation.

Acute Toxicity

Component Information

Cocaine Hydrochloride - 53-21-4

LD50/oral/rat = No information available

LD50/oral/mouse = 96 mg/kg Oral LD50 Mouse LD50/dermal/rabbit = No information available LD50/dermal/rat = No information available LC50/inhalation/rat = No information available LC50/inhalation/mouse = No information available

Other LD50 or LC50information = No information available

Product Information

LD50/oral/rat =

VALUE- Acute Tox Oral = No information available

LD50/oral/mouse =

Value - Acute Tox Oral = 96mg/kg

LD50/dermal/rabbit

VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat

VALUE -Acute Tox Dermal = No information available

LC50/inhalation/rat

VALUE-Vapor = No information available VALUE-Gas = No information available VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse

VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: Causes skin irritation.

Eye Contact: Causes serious eye irritation.

Inhalation May cause irritation of respiratory tract. May affect behavior/central nervous system.

IngestionToxic if swallowed. May cause central nervous system effects (affect behavior).

Aspiration hazard No information available

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

Chronic Toxicity Skin: Prolonged or repeated skin contact may cause allergic skin reaction..

Sensitization: May cause sensitization by skin contact

Product code: C1408 Product name: COCAINE 7 / 12
HYDROCHLORIDE (CII), USP

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic

Components	IARC	ACGIH -	NTP	OSHA HCS -	Australia - Notifiable	Australia - Prohibited
		Carcinogens		Carcinogens	Carcinogenic	Carcinogenic
					Substances	Substances
Cocaine Hydrochloride	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

Reproductive toxicity

May damage fertility or the unborn child

Reproductive Effects: Placental abruption and vascular disruption. Placental abruption associated with

maternal cocaine abuse during pregnancy appears to result from vascular disruption

Developmental Effects: Behavioral and central nervous system effects and congenital anomalies

(developmental effects) on newborn. This may also be associated with maternal

cocaine abuse during pregnancy resulting from vascular disruption.

Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure STOT - repeated exposure

Target Organs:

central nervous system. No information available No information available

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Bioaccumulative potential: No information available

Mobility: No information available

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:

Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:

Empty containers should be taken for local recycling, recovery or waste disposal

Components	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Cocaine Hydrochloride	None	None	None	None

Product code: C1408 Product name: COCAINE 8 / 12

HYDROCHLORIDE (CII), USP

14. TRANSPORT INFORMATION

DOT

UN-No: UN1544

Proper Shipping Name: Alkaloids, solid, n.o.s.(cocaine hydrochloride)

Hazard Class: 6.1

Subsidiary Risk: No information available

Packing Group: III ERG No: 151

Marine PollutantNo data availableDOT RQ (lbs):No information availableSpecial ProvisionsNo Information available

Symbol(s): G

TDG (Canada)

UN-No: UN1544

Proper Shipping Name: Alkaloid salts, solid, n.o.s. (cocaine hydrochloride)

Hazard Class: 6.1

Subsidiary Risk: No information available

Packing Group:

Marine Pollutant No Information available

ADR

UN-No: UN1544

Proper Shipping Name: Alkaloids, solid, n.o.s.(cocaine hydrochloride)

Hazard Class: 6.1
Packing Group: III

Subsidiary Risk: No information available

IMO / IMDG

UN-No: UN1544

Proper Shipping Name: Alkaloids, solid, n.o.s. (cocaine hydrochloride)

Hazard Class: 6.1

Subsidiary Risk: No information available

Packing Group:

Marine Pollutant No information available

EMS: F-A

RID

UN-No: UN1544

Proper Shipping Name: Alkaloids, solid, n.o.s.(cocaine hydrochloride)

Hazard Class: 6.1

Subsidiary Risk: No information available

Packing Group:

ICAO

UN-No: UN1544

Proper Shipping Name: Alkaloid salts, solid, n.o.s.(cocaine hydrochloride)

Hazard Class: 6.1

Subsidiary Risk: No information available

Packing Group:

IATA

UN-No: UN1544

Proper Shipping Name: Alkaloids, solid, n.o.s. (cocaine hydrochloride)

Product code: C1408 Product name: COCAINE HYDROCHLORIDE (CII), USP

14. TRANSPORT INFORMATION

Hazard Class: 6.1

Subsidiary Risk: No information available

Packing Group: Ш **ERG Code:** 6L

Special Provisions No information available

15. REGULATORY INFORMATION

International Inventories

Components	U.S. TSCA	KOREA KECL	Philippines	Japan ENCS	CHINA	Australia	EINECS-No.
			(PICCS)			(AICS)	
Cocaine Hydrochloride	Not Listed	Not present	Present 200-167-1				

U.S. Regulations

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Components	Carcinogen	Developmental Toxicity	Male Reproductive	Female Reproductive
			Toxicity	Toxicity:
Cocaine Hydrochloride	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Components	CERCLA - Hazardous	Section 302 Extremely	Section 302 Extremely	Section 313 -	Section 313 - Reporting
	Substances and their	Hazardous	Hazardous	Chemical Category	de minimis
	Reportable Quantities	Substances and TPQs	Substances and RQs		
Cocaine Hydrochloride	None	None	None	None	None

U.S. TSCA

	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Cocaine Hydrochloride	Not Applicable	Not Applicable

Canada

WHMIS hazard class:

D1B Toxic materials

D2B Toxic materials

Canada Controlled Products Regulation:

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

Inventory

Components	Canada (DSL)	Canada (NDSL)
Cocaine Hydrochloride	Not Listed	Not Listed

10/12 Product code: C1408 **Product name: COCAINE**

Components	CEPA Schedule I - Toxic Substances
Cocaine Hydrochloride	Not listed

Components	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Cocaine Hydrochloride	Not listed

EU Classification

R-phrase(s)

R25 - Toxic if swallowed.

<u>S -phrase(s)</u>
S45 - In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

Components	Classification	Concentration Limits:	Safety Phrases
Cocaine Hydrochloride		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:

T - Toxic



16. OTHER INFORMATION

Product code: C1408

Product name: COCAINE HYDROCHLORIDE (CII), USP

16. OTHER INFORMATION

Preparation Date:7/1/2016Revision Date:7/1/2016Prepared by:Sonia Owen

Disclaimer: All chemicals may pose unknown hazards and should be used with caution. This

Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet

Product code: C1408 Product name: COCAINE 12 / 12

HYDROCHLORIDE (CII), USP



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
C1408	Cocaine 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,

Oralia Chavez

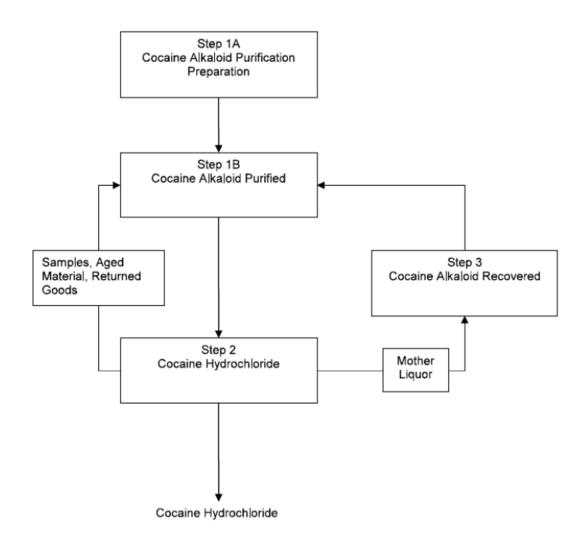
Quality Assurance Specialist

Order Clony



Manufacturing Process Flowchart

Cocaine Hydrochloride (CII), USP (Cat# C1408)



CORPORATE HEADQUARTERS

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



C1408, Cocaine 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

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.



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 30 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 - Cocaine Hydrochloride (CII), USP (Cat# C1408)

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
Arsenic	As	1	< 3 ppm
Nickel	Ni	2A	< 20 ppm
Thallium	TI	2B	Not tested
Gold	Au	2B	Not tested
Palladium	Pd	2B	Not tested
Iridium	Ir	2B	Not tested
Osmium	Os	2B	Not tested
Rhodium	Rh	2B	Not tested
Ruthenium	Ru	2B	Not tested
Selenium	Se	2B	Not tested
Silver	Ag	2B	Not tested
Platinum	Pt	2B	Not tested
Lithium	Li	3	Not tested
Antimony	Sb	3	Not tested
Barium	Ba	3	Not tested
Molybdenum	Мо	3	Not tested
Copper	Cu	3	Not tested
Tin	Sn	3	Not tested
Chromium	Cr	3	Not tested

Elements indicated as "Not tested" are not intentionally added to the manufacturing process.

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.

CORPORATE HEADQUARTERS

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



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



RE: Residual Solvents - Cocaine Hydrochloride (CII), USP (Cat# C1408)

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
Cyclohexane	2	< 3880 ppm
Methanol	2	< 3000 ppm
Acetone	3	< 5000 ppm
Ethanol	3	< 5000 ppm
Naphtha		< 0.10%

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.

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Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication. Below you will find a typical label example for this catalog item.



Spectrum Chemical Mfg Corp