

Scientific Documentation

Carbamazepine, 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 Carbamazepine, USP (CA250)

Item Number	CA250
Item	Carbamazepine, USP
CAS Number	298-46-4
Molecular Formula	C ₁₅ H ₁₂ N ₂ O
Molecular Weight	236.27
MDL Number	
Synonyms	5H-Dibenz(b,f)azepine-5-carboxamide

Test	Specification	
	Min	Max
ASSAY (DRIED BASIS)	98.0%	102.0%
X-RAY DIFFRACTION	CONFORMS	
ACIDITY		1.0 ml/g
ALKALINITY		1.0 ml/g
LOSS ON DRYING		0.5%
RESIDUE ON IGNITION		0.1%
CHLORIDE (Cl)		0.014%
ELEMENTAL IMPURITIES:		
NICKEL (Ni)	AS REPORTED	
CHROMIUM (Cr)	AS REPORTED	
MOLYBDENUM (Mo)	AS REPORTED	
ORGANIC IMPURITIES:		
RELATED COMPOUND A		0.2 %
RELATED COMPOUND B		0.2 %
UNSPECIFIED IMPURITY		0.2 %
TOTAL IMPURITIES		0.5 %
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE	
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD	
EXPIRATION DATE		

Test	Specification	
	Min	Max
DATE OF MANUFACTURE		
APPEARANCE		
RESIDUAL SOLVENTS	AS REPORTED	

Spectrum Chemical Mfg Corp

<i>Corporate Headquarters:</i>	<i>West Coast Facility:</i>
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	CA250	Lot Number	2LD0027
Item	Carbamazepine, USP	Manufacturer Lot	22CT000003
CAS Number	298-46-4	Manufacturer Code	14126
Molecular Formula	C ₁₅ H ₁₂ N ₂ O	Molecular Weight	236.27

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (DRIED BASIS)	98.0%	102.0%	99.6%
X-RAY DIFFRACTION	CONFORMS		CONFORMS
ACIDITY		1.0 ml/g	<1.0 ml/g
ALKALINITY		1.0 ml/g	<1.0 ml/g
LOSS ON DRYING		0.5%	0.2%
RESIDUE ON IGNITION		0.1%	<0.1%
CHLORIDE (Cl)		0.014%	<0.014%
ELEMENTAL IMPURITIES:			COMPLIES WITH STANDARD
NICKEL (Ni)	AS REPORTED		0.35 ppm
CHROMIUM (Cr)	AS REPORTED		<0.5 ppm
MOLYBDENUM (Mo)	AS REPORTED		<300 ppm
ORGANIC IMPURITIES:			.
RELATED COMPOUND A		0.2 %	0.0%
RELATED COMPOUND B		0.2 %	0.0%
UNSPECIFIED IMPURITY		0.2 %	0.0%
TOTAL IMPURITIES		0.5 %	0.0%
IDENTIFICATION A (FTIR)	SPECTRUM MATCHES REFERENCE		SPECTRUM MATCHES REFERENCE
IDENTIFICATION (B)	RETENTION TIME CORRESPONDS TO STANDARD		RETENTION TIME CORRESPONDS TO STANDARD
EXPIRATION DATE			31-AUG-2026
DATE OF MANUFACTURE			01-SEP-2021

TEST	SPECIFICATION		RESULT
	MIN	MAX	
APPEARANCE			WHITE POWDER
RESIDUAL SOLVENTS	AS REPORTED		COMPLIES WITH STANDARD

Certificate of Analysis Results Entered By:

GHERRERA
Genaro Herrera
27-MAY-22 10:48:38

Spectrum Chemical Mfg Corp
755 Jersey Avenue
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AWILLIAMS
Allison Williams
31-MAY-22 06:10:56

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 CTX Lifesciences Pvt. Ltd. at 251-252, Sachin Magdalla Road, GIDC Sachin,, Surat, Gujarat 394230, India (IND). 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 22-August-2022

Revision Number 2

1. Identification

Product identifier

Product Name CARBAMAZEPINE, USP

Other means of identification

Product Code(s) CA250

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use No information available

Restrictions on use No information available

Details of the supplier of the safety data sheet

Supplier Address

Spectrum Chemical Mfg. Corp.
14422 South San Pedro St.
Gardena, CA 90248
(310) 516-8000

Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300

2. Hazard(s) identification

Classification

Acute toxicity - Oral	Category 4
Skin sensitization	Category 1A
Reproductive toxicity	Category 1A

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Danger

Hazard statements

Harmful if swallowed
May cause an allergic skin reaction
May damage fertility or the unborn child



Appearance Crystalline powder or 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
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
If skin irritation or rash occurs: Get medical advice/attention
Wash contaminated clothing before reuse
IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell
Rinse mouth

Precautionary Statements - Storage

Store locked up.

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

Very toxic to aquatic life with long lasting effects. Very toxic to aquatic life.

3. Composition/information on ingredients

Substance

Chemical name	CAS No	Weight-%	Trade secret
Carbamazepine	298-46-4	100	*

*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 with soap and water. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a physician.

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	Itching. Rashes. Hives.
-----------------	-------------------------

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. Nitrogen oxides (NOx).
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.
-----------------------------	--

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.
--------------------------------	--

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. Store locked up.

8. Exposure controls/personal protection**Control parameters****Exposure Limits**

The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

Appropriate engineering controls**Engineering controls**

Showers
Eyewash stations
Ventilation systems.

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.

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.

9. Physical and chemical properties**Information on basic physical and chemical properties**

Physical state	Solid
Appearance	Crystalline powder or powder
Color	White to Off-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	190 °C / 374 °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	Practically insoluble in water	None known
Solubility(ies)	Soluble in Alcohol	None known

	Soluble in Acetone	
	Soluble in Chloroform	
	Slightly soluble in acetic acid	
Partition coefficient	No data available	None known
Autoignition temperature	no data available	None known
Decomposition temperature		None known
Kinematic viscosity	no data available	None known
Dynamic viscosity	No data available	None known

Other information

Explosive properties	No information available
Oxidizing properties	No information available
Softening point	No information available
Molecular weight	No information available
VOC Content (%)	No information available
Liquid Density	No information available
Bulk density	No information available

10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under 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	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).
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	Itching. Rashes. Hives.
-----------------	-------------------------

Acute toxicity

Numerical measures of toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Carbamazepine 298-46-4	= 1957 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. May damage 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 Very toxic to aquatic life with long lasting effects.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Carbamazepine 298-46-4	-	LC50: =43mg/L (96h, Brachydanio rerio)	-	EC50: =0.414mg/L (48h, Daphnia magna) EC50: =92mg/L (24h, Daphnia magna)

Persistence and degradability	No information available.
Bioaccumulation	Inherently biodegradable.

Component Information

Chemical name	Partition coefficient
Carbamazepine 298-46-4	1.76

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

<u>DOT</u>	not regulated
<u>TDG</u>	not regulated
<u>MEX</u>	not regulated

<u>ICAO (air)</u>	not regulated
<u>IATA</u>	not regulated
<u>IMDG</u>	not regulated
<u>RID</u>	not regulated
<u>ADR</u>	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 complies with China:
KECL	Complies
PICCS	Complies
AICS	All the constituents of this material are listed on the Australian Inventory of Chemical Substances (AICS).

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances

US Federal Regulations

SARA 313

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

SARA 311/312 Hazard Categories

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

CWA (Clean Water Act)

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

CERCLA

This material, as supplied, 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 contains the following Proposition 65 chemicals:.

Chemical name	California Proposition 65
Carbamazepine - 298-46-4	developmental toxicity

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 22-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
CA250	Carbamazepine, USP

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

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

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

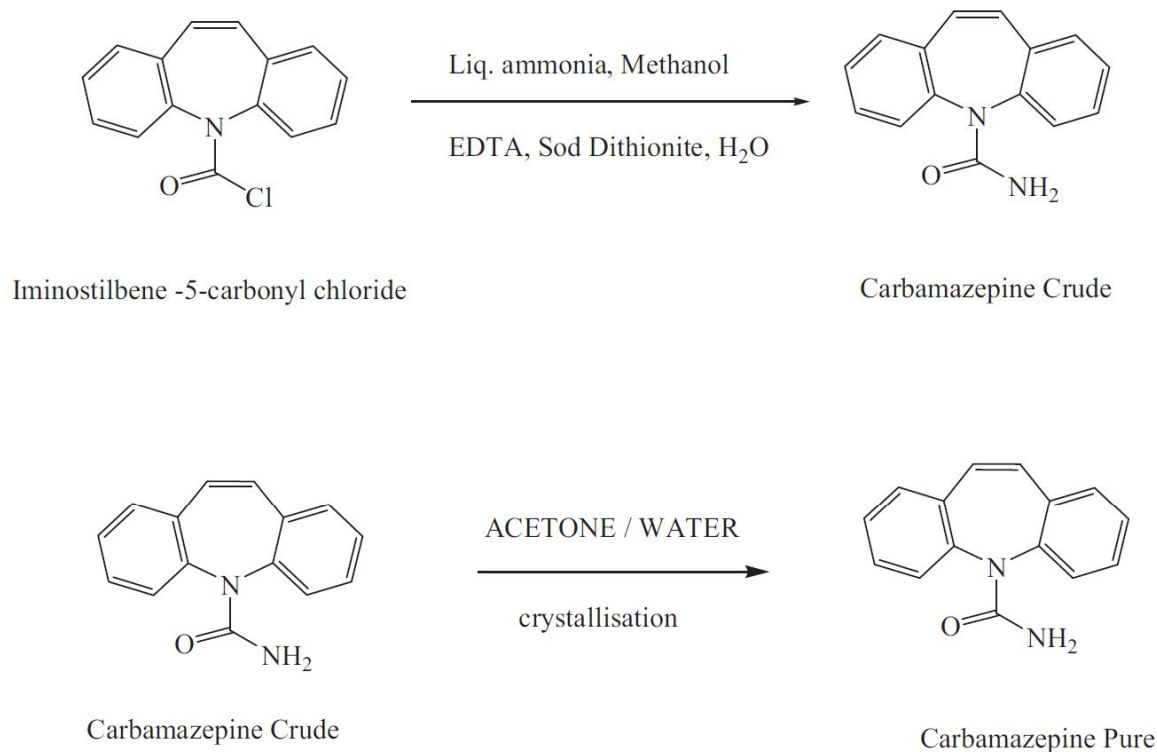
Sincerely,

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

Oralia Chavez
Quality Assurance Specialist

Manufacturing Process Flowchart Carbamazepine, USP (Cat# CA250)

Reaction Scheme of Carbamazepine



Brief Manufacturing process

Iminostilbene carbonyl chloride is reacted with Liq. ammonia in methanol to give Carbamazepine crude. Carbamazepine Crude is purified by Crystallization in Acetone and water mixture .

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

CA250, Carbamazepine, 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 this material 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 by Spectrum Chemical Mfg. Corp.

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 60 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 – Carbamazepine, USP (Cat# CA250)

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
Nickel	Ni	2A	< 20 ppm
Molybdenum	Mo	3	< 300 ppm
Chromium	Cr	3	< 1100 ppm

Other elemental impurities considered by USP <232>, <233> and ICH Q3D which are not addressed in the above mentioned table are not likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

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

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

Sincerely,

Technical Services
Spectrum Chemical Mfg. Corp.

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

CORPORATE HEADQUARTERS

769 Jersey Avenue

New Brunswick, NJ 08901

PHONE 732.214.1300

FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street

Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843



RE: Residual Solvents – Carbamazepine, USP (Cat# CA250)

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
Benzene	1	< 2 ppm
Chlorobenzene	2	< 360 ppm
Methanol	2	< 3000 ppm
Toluene	2	< 890 ppm
Acetone	3	< 5000 ppm
Ethanol	3	< 5000 ppm

No 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.

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.

Exp. Date: 00-00-0000



DANGER
 • Harmful if swallowed • May cause an allergic skin reaction • May damage fertility or the unborn child.
 • 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 • Wash face, hands and any exposed skin thoroughly after handling • Contaminated work clothing must not be allowed out of the workplace.
FIRST AID: IF ON SKIN: Wash with plenty of water. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical attention. IF SWALLOWED: Call a POISON CENTER or physician if you feel unwell. Rinse mouth.

KEEP FROM CHILDREN



CA250 **SIZ SY**

Carbamazepine
 (5*H*-Dibenz[*b,f*]azepine-5-carboxamide)
 USP
 CAS 298-46-4

USP 800
 HAZARDOUS DRUG

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

$C_{15}H_{12}N_2O$ F.W. 236.27

Manufacturer/Supplier Code ?
 Manufacturer Lot Number ?

Assay (Dried Basis) 98.0-102.0%
 X-Ray Diffraction Conforms

MAXIMUM LIMITS

Acidity To pass test
 Alkalinity To pass test
 Loss on Drying 0.5%
 Residue on Ignition 0.1%
 Chloride (Cl) 0.014%
 Elemental Impurities As reported

Organic Impurities:
 Carbamazepine Related Compound A 0.2%
 Carbamazepine Related Compound B 0.2%
 Individual Unspecified Impurity 0.2%
 Total Impurities 0.5%
 Residual Solvents To pass test

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

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

G 15/J2GHS-A ?

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