

# **Scientific Documentation**

# Coal Tar, 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) General Label Information – Sample Label



# **Specification for Coal Tar, USP (C1290)**

Item Number	C1290
Item	Coal Tar, USP
CAS Number	8007-45-2
Molecular Formula	
Molecular Weight	
MDL Number	
Synonyms	Pix Carbonis ; Crude Coal Tar ; Pix Lithanthracis

Test	Specification	Specification	
	Min	Max	
RESIDUE ON IGNITION		2.0 %	
ELEMENTAL IMPURITIES	AS REPORTED		
IDENTIFICATION	BLUE FLUORESCENCE DEVELOPES		
EXPIRATION 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	C1290	Lot Number	1LL0883
Item	Coal Tar, USP	CAS Number	8007-45-2

тгст	SPECIFICATION		DECULT
TEST	MIN	MAX	RESULT
RESIDUE ON IGNITION		2.0 %	0.3 %
ELEMENTAL IMPURITIES	AS REPORTED		NO ELEMENTAL IMPURITIES PRESENT
IDENTIFICATION	BLUE FLUORESCENCE DEVELOPES		BLUE FLUORESCENCE DEVELOPES
EXPIRATION DATE			08-DEC-2024
DATE OF MANUFACTURE			08-DEC-2022
APPEARANCE			BLACK VISCOUS LIQUID
RESIDUAL SOLVENTS	AS REPORTED		NO RESIDUAL SOLVENTS USED
MONOGRAPH EDITION			(USP) 2022

Certificate of Analysis Results Entered By:

HBERMUDEZ Hernan Bermudez 13-JAN-23 11:31:41

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

Certificate of Analysis Results Approved By:

JRUIZ Jesus Ruiz 13-JAN-23 16:30:32 exceeded in the formulation of pharmaceutical products.

# SAFETY DATA SHEET

Revision date 21-April-2023

1. Identification		
Product identifier		
Product Name	COAL TAR, USP	
Other means of identification		
Product Code(s)	C1290	
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**

Serious eye damage/eye irritation	Category 2B
Germ cell mutagenicity	Category 1B
Carcinogenicity	Category 1A
Reproductive toxicity	Category 1B
Specific target organ toxicity (single exposure)	Category 3

# Hazards not otherwise classified (HNOC)

Not applicable

# Label elements

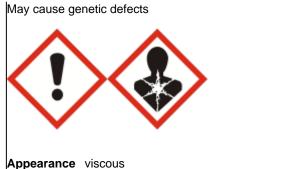
Danger

### Hazard statements

Causes eye irritation May cause respiratory irritation May damage fertility or the unborn child May cause cancer



**Revision Number** 2



Physical state Liquid

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

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

### Unknown acute toxicity

# Other information

May be harmful if swallowed.

# 3. Composition/information on ingredients

# Substance

Chemical name	CAS No	Weight-%
Coal Tar	8007-45-2	100

# 4. First-aid measures

## **Description of first aid measures**

General advice	Show this safety data sheet to the doctor in attendance. IF exposed or concerned: Get medical advice/attention.
Inhalation	Remove to fresh air. IF exposed or concerned: Get medical advice/attention.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Get medical attention if irritation develops and persists. Remove contact lenses, if present and easy to do. Continue rinsing.

Skin contact	Wash skin with soap and water.
Ingestion	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.
Most important symptoms and effect	ts, 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.	
Explosion data Sensitivity to mechanical impac	t 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. Avoid contact with skin, eyes or clothing.	
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. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes.

# Conditions for safe storage, including any incompatibilities

Storage ConditionsKeep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach<br/>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, suc	ch as personal protective equipment	
Eye/face protection	If splashes are likely to occur, wear safety glasses with side-shields. None required for consumer use.	
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. Avoid contact with skin, eyes or clothing.	

# 9. Physical and chemical properties

Information on basic physical and chemical properties		
Physical state	Liquid	
Appearance	viscous	
Color	black	
Odor	No information available	
Odor threshold	No information available	
<u>Property</u>	<u>Values</u>	Remarks • Method
рН	no data available	None known
Melting point / freezing point	95 - 118 °C / 203 - 244.4 °F	None known
Boiling point / boiling range	> 150 °C / >302 °F	None known
Flash point	96 °C / 204.8 °F	CC (closed cup)
Evaporation rate	no data available	None known
Flammability (solid, gas)	no data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive	No data available	
limits		
Lower flammability or explosive	No data available	
limits		
Vapor pressure	No data available	None known
Vapor density	>1	None known
Relative density	1.2	None known
Water solubility	Insoluble in water	None known
Solubility(ies)	Partially soluble in methanol	None known
	Partially soluble in diethyl ether	

	Partially soluble in alcohol	
	Soluble in Benzene	
	Soluble in Nitrobenzene	
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 reactivit	tv	
To: Otability and reactivity	l y	

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. Causes eye irritation. May cause redness, itching, and pain.	
Skin contact	Specific test data for the substance or mixture is not available.	
Ingestion	Specific test data for the substance or mixture is not available. Harmful if swallowed. (based on components).	
Symptoms related to the physical, chemical and toxicological characteristics		
Symptoms	May cause redness and tearing of the eyes.	
Acute toxicity		
Numerical measures of toxicity		

Unknown acute toxicity

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Coal Tar 8007-45-2	= 1700 mg/kg (Rat)	= 15800 mg/kg (Rabbit)	-

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

Skin corrosion/irritation Serious eye damage/eye irritation Respiratory or skin sensitization	May cause skin irritation. Classification based on data available for ingredients. Irritating to eyes. No information available.
Germ cell mutagenicity	Contains a known or suspected mutagen. Classification based on data available for ingredients. May cause genetic defects.
Carcinogenicity	Contains a known or suspected carcinogen. Classification based on data available for ingredients. May cause cancer.

ingredients. May cause cancer. The table below indicates whether each agency has listed any ingredient as a carcinogen.

_		mileater each ageney had			
	Chemical name	ACGIH	IARC	NTP	OSHA
	Coal Tar	-	Group 1 - Carcinogenic	-	-
	8007-45-2		to humans - Supplement		
			7 [1987] see coal-tar		
			distillation RR-56753-3 in		
			Monograph 100F		
			Monograph 35 [1985]		

# Legend

Reproductive toxicity	No information available.
STOT - single exposure STOT - repeated exposure Target organ effects	No information available. No information available. kidney, respiratory system, Skin, Urinary Tract, Bladder, lungs.
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 Bioaccumulation	No information available. Inherently biodegradable.
Other adverse effects	No information available.

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

13. Disposal considerations

DOT	not regulated
TDG	not regulated

MEX	not regulated
ICAO (air)	not regulated
IATA	not regulated
IMDG	not regulated
RID	not regulated
ADR	not regulated
ADN	not regulated

# 15. Regulatory information

International Inventories

TSCA	Complies
	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, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302).

Chemical name	Hazardous Substances RQs	Extremely Hazardous Substances RQs
Coal Tar	1 lb. final RQ; 0.454 kg final RQ (coke	-
8007-45-2	oven emissions)	

# US State Regulations

# **California Proposition 65**

This product contains the following Proposition 65 chemicals:.

Chemical name	California Proposition 65
Coal Tar - 8007-45-2	carcinogen

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

Chemical name	New Jersey	Massachusetts	Pennsylvania
Coal Tar	sn 4005	Present	Environmental hazard
8007-45-2			Special hazardous substance

### U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

# 16. Other information

NFPA Health hazards 1 Flammability 1 Instability 0 Physical and chemical properties -HMIS Health hazards 1\* Flammability 1 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 (time-weighted average) TWA STEL STEL (Short Term Exposure Limit) Ceiling Maximum limit value Key literature references and sources for data used to compile the SDS Agency for Toxic Substances and Disease Registry (ATSDR) U.S. Environmental Protection Agency ChemView Database European Food Safety Authority (EFSA) EPA (Environmental Protection Agency) Acute Exposure Guideline Level(s) (AEGL(s)) U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act U.S. Environmental Protection Agency High Production Volume Chemicals Food Research Journal Hazardous Substance Database International Uniform Chemical Information Database (IUCLID) Japan GHS Classification Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS) NIOSH (National Institute for Occupational Safety and Health) National Library of Medicine's ChemID Plus (NLM CIP) National Library of Medicine's PubMed database (NLM PUBMED) National Toxicology Program (NTP) New Zealand's Chemical Classification and Information Database (CCID) Organization for Economic Co-operation and Development Environment, Health, and Safety Publications Organization for Economic Co-operation and Development High Production Volume Chemicals Program Organization for Economic Co-operation and Development Screening Information Data Set World Health Organization

### **Revision date**

21-April-2023

No information available.

Revision Note 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
C1290	Coal Tar, 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

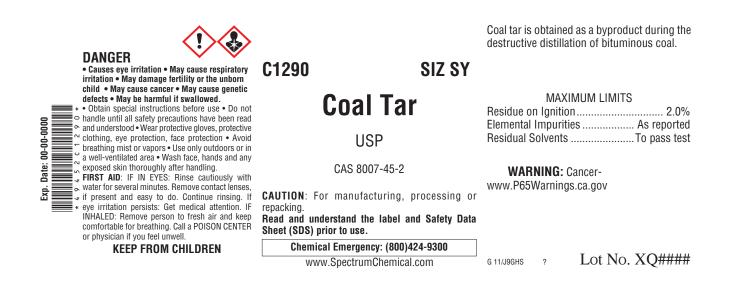
Sincerely, Quality Assurance Spectrum Chemical Mfg. Corp.

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

# spectrum®

# **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

# Corporate Headquarters:

769 Jersey Ave. New Brunswick, NJ 08901 West Coast Facility: 14422 S. San Pedro St. Gardena, CA 90248 310.516.8000

732.214.1300